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PART 1300—DEFINITIONS

Sec. 1300.01 Definitions relating to controlled substances.
1300.02 Definitions relating to listed chemicals.

AUTHORITY: 21 U.S.C. 802, 871(b), 951, 958(f)

SOURCE: 62 FR 13941, Mar. 24, 1997, unless otherwise noted.

§ 1300.01 Definitions relating to controlled substances.

(a) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802), except that certain terms used in part 1316 of this chapter are defined at the beginning of each subpart of that part.

(b) As used in parts 1301 through 1308 and part 1312 of this chapter, the following terms shall have the meanings specified:


(2) The term Administration means the Drug Enforcement Administration.

(3) The term Administrator means the Administrator of the Drug Enforcement Administration. The Administrator has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

(4) The term anabolic steroid means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progesterins, and corticosteroids) that promotes muscle growth, and includes:

(i) Boldenone;
(ii) Chlorotestosterone (4-chlorotestosterone);
(iii) Clostebol;
(iv) Dehydrochlormethyltestosterone;
(v) Dihydrotestosterone (4-dihydrotestosterone);
(vi) Drostanolone;
(vii) Ethylestrenol;
(viii) Fluoxymesterone;
(ix) Formebulone (formebolone);
(x) Mesterolone;
(xi) Methandienone;
(xii) Methandrostenolone;
(xiii) Methandriol;
(xiv) Methandrostenediolone;
(xv) Methenolone;
(xvi) Methylandrostenediolone;
(xvii) Mibolerone;
(xviii) Nandrolone;
(xix) Norandrosterone;
(xx) Oxandrolone;
(xx) Oxymetholone;
(xxx) Stanolone;
(xxxx) Stanozolol;
(xxxxx) Testolactone;
(xxxxxx) Testosterone;
(xxxxxx) Trenbolone; and
(xxxxxxx) Any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth. Except such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration. If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this paragraph.

(5) The term basic class means, as to controlled substances listed in Schedules I and II:

(i) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in §1308.11(b) of this chapter;

(ii) Each of the opium derivatives, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in §1308.11(c) of this chapter;

(iii) Each of the hallucinogenic substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in §1308.11(d) of this chapter;

(iv) Each of the following substances, whether produced directly or indirectly...
by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;

(B) Apomorphine;

(C) Codeine;

(D) Etorphine hydrochloride;

(E) Ethylmorphine;

(F) Hydromorphone;

(G) Metopon;

(I) Oxycodone;

(J) Oxymorphone;

(K) Thebaine;

(L) Mixed alkaloids of opium listed in Section 1308.12(b)(2) of this chapter;

(N) Cocaine; and

(O) Ecgonine;

(v) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in §1308.12(c) of this chapter; and

(vi) Methamphetamine, its salts, isomers, and salts of its isomers;

(vii) Amphetamine, its salts, optical isomers, and salts of its optical isomers;

(viii) Phenmetrazine and its salts;

(ix) Methylphenidate;

(x) Each of the substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in §1308.12(e) of this chapter.

(6) The term commercial container means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term commercial container does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drum, or other package in which commercial containers are stored or are used for shipment of controlled substances.

(7) The term compounder means any person engaging in maintenance or detoxification treatment who also mixes, prepares, packages or changes the dosage form of a narcotic drug listed in Schedules II, III, IV or V for use in maintenance or detoxification treatment by another narcotic treatment program.

(8) The term controlled substance has the meaning given in section 802(6) of Title 21, United States Code (U.S.C.).

(9) The term customs territory of the United States means the several States, the District of Columbia, and Puerto Rico.

(10) The term detoxification treatment means the dispensing, for a period of time as specified below, of a narcotic drug or narcotic drugs in decreasing doses to an individual to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period of time. There are two types of detoxification treatment: Short-term detoxification treatment and long-term detoxification treatment.

(i) Short-term detoxification treatment is for a period not in excess of 30 days.

(ii) Long-term detoxification treatment is for a period more than 30 days but not in excess of 180 days.

(11) The term dispenser means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

(12) The term export means, with respect to any article, any taking out or removal of such article from the jurisdiction of the United States (whether or not such taking out or removal constitutes an exportation within the meaning of the customs and related laws of the United States).

(13) The term exporter includes every person who exports, or who acts as an export broker for exportation of, controlled substances listed in any schedule.

(14) The term hearing means:

(i) In part 1301 of this chapter, any hearing held for the granting, denial,
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revocation, or suspension of a registration pursuant to sections 303, 304, and 1008 of the Act (21 U.S.C. 823, 824 and 958).

(ii) In part 1303 of this chapter, any hearing held regarding the determination of aggregate production quota or the issuance, adjustment, suspension, or denial of a procurement quota or an individual manufacturing quota.

(iii) In part 1306 of this chapter, any hearing held for the issuance, amendment, or repeal of any rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).

(15) The term import means, with respect to any article, any bringing in or introduction of such article into either the jurisdiction of the United States or the customs territory of the United States, and from the jurisdiction of the United States into the customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(16) The term importer includes every person who imports, or who acts as an import broker for importation of, controlled substances listed in any schedule.

(17) The term individual practitioner means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

(18) The term institutional practitioner means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

(19) The term interested person means any person adversely affected or aggrieved by any rule or proposed rule issued pursuant to section 201 of the Act (21 U.S.C. 811).

(20) The term inventory means all factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor).

(21) The term isomer means the optical isomer, except as used in §1308.11(d) and §1308.12(b)(4) of this chapter. As used in §1308.11(d) of this chapter, the term isomer means the optical, positional, or geometric isomer. As used in §1308.12(b)(4) of this chapter, the term isomer means the optical or geometric isomer.

(22) The term jurisdiction of the United States means the customs territory of the United States, the Virgin Islands, the Canal Zone, Guam, American Samoa, and the Trust Territories of the Pacific Islands.

(23) The term label means any display of written, printed, or graphic matter placed upon the commercial container of any controlled substance by any manufacturer of such substance.

(24) The term labeling means all labels and other written, printed, or graphic matter:

(i) Upon any controlled substance or any of its commercial containers or wrappers, or

(ii) Accompanying such controlled substance.

(25) The term Long Term Care Facility (LTCF) means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

(26) The term maintenance treatment means the dispensing for a period in excess of twenty-one days, of a narcotic drug or narcotic drugs in the treatment of an individual for dependence upon heroin or other morphine-like drug.

(27) The term manufacture means the producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his/her administration or dispensing such
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substance in the course of his/her professional practice, prepares, compounds, packages or labels such substance. The term manufacturer means a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.

(28) The term mid-level practitioner means an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants who are authorized to dispense controlled substances by the state in which they practice.

(29) The term name means the official name, common or usual name, chemical name, or brand name of a substance.

(30) The term narcotic drug means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(i) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(ii) Poppy straw and concentrate of poppy straw.

(iii) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine and derivatives of ecgonine or their salts have been removed.

(iv) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(v) Ecgonine, its derivatives, their salts, isomers and salts of isomers.

(vi) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in paragraphs (b)(31)(i) through (v) of this section.

(31) The term narcotic treatment program means a program engaged in maintenance and/or detoxification treatment with narcotic drugs.

(32) The term net disposal means, for a stated period, the quantity of a basic class of controlled substance distributed by the registrant to another person, plus the quantity of that basic class used by the registrant in the production of (or converted by the registrant into) another basic class of controlled substance or a noncontrolled substance, plus the quantity of that basic class otherwise disposed of by the registrant, less the quantity of that basic class returned to the registrant by any purchaser, and less the quantity of that basic class distributed by the registrant to another registered manufacturer of that basic class for purposes other than use in the production of, or conversion into, another basic class of controlled substance or a noncontrolled substance or in the manufacture of dosage forms of that basic class.

(33) The term pharmacist means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.

(34) The term person includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(35) The term proceeding means all actions taken for the issuance, amendment, or repeal of any rule issued pursuant to section 201 of the Act (21 U.S.C. 811), commencing with the publication by the Administrator of the...
(37) The term *purchaser* means any registered person entitled to obtain and execute order forms pursuant to §§1305.04 and 1305.06.

(38) The term *readily retrievable* means that certain records are kept by automatic data processing systems or other electronic or mechanized record-keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

(39) The term *register* and *registration* refer only to registration required and permitted by sections 303 or 1007 of the Act (21 U.S.C. 823 or 957).

(40) The term *registrant* means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

(41) The term *supplier* means any registered person entitled to fill order forms pursuant to §1305.08 of this chapter.

(42) The term *freight forwarding facility* means a separate facility operated by a distributing registrant through which sealed, packaged controlled substances in unmarked shipping containers (i.e., the containers do not indicate that the contents include controlled substances) are, in the course of delivery to, or return from, customers, transferred in less than 24 hours. A distributing registrant who operates a freight forwarding facility may use the facility to transfer controlled substances from any location the distributing registrant operates that is registered with the Administration to manufacture, distribute, or import controlled substances, or, with respect to returns, registered to dispense controlled substances, provided that the notice required by §1301.12(b)(4) of Part 1301 of this chapter has been submitted and approved. For purposes of this definition, a distributing registrant is a person who is registered with the Administration as a manufacturer, distributor, and/or importer.

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bringing in or introduction of such listed chemical into either the jurisdiction of the United States or into the Customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(8) The term chemical importer is a regulated person who, as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the United States.

(9) The term chemical mixture means a combination of two or more chemical substances, at least one of which is not a listed chemical, except that such term does not include any combination of a listed chemical with another chemical that is present solely as an impurity or which has been created to evade the requirements of the Act.

(10) The term customs territory of the United States means the several States, the District of Columbia, and Puerto Rico.

(11) The term encapsulating machine means any manual, semi-automatic, or fully automatic equipment which may be used to fill shells or capsules with any powdered, granular, semi-solid, or liquid material.

(12) The term established business relationship with a foreign customer means the regulated person has exported a listed chemical at least once within the past six months, or twice within the past twelve months to a foreign manufacturer, distributor, or end user of the chemical that has an established business in the foreign country with a fixed street address. A person or business which functions as a broker or intermediary is not a customer for purposes of this definition. The term also means that the regulated person has provided the Administration with the following information in accordance with the waiver of the 15-day advance notice requirements of §1313.24 of this chapter:

(i) The name and street address of the chemical exporter and of each regular customer;
(ii) The telephone number, telex number, contact person, and where available, the facsimile number for the chemical exporter and for each regular customer;
(iii) The nature of the regular customer’s business (i.e., importer, exporter, distributor, manufacturer, etc.), and if known, the use to which the listed chemical or chemicals will be applied;
(iv) The duration of the business relationship;
(v) The frequency and number of transactions occurring during the preceding 12-month period;
(vi) The amounts and the listed chemical or chemicals involved in regulated transactions between the chemical exporter and regular customer;
(vii) The method of delivery (direct shipment or through a broker or forwarding agent); and
(viii) Other information that the chemical exporter considers relevant for determining whether a customer is a regular customer.

(13) The term established record as an importer means that the regulated person has imported a listed chemical at least once within the past six months, or twice within the past twelve months from a foreign supplier. The term also means that the regulated person has provided the Administration with the following information in accordance with the waiver of the 15-day advance notice requirements of §1313.15 of this chapter:

(i) The name, DEA registration number (where applicable), street address, telephone number, telex number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and
(ii) The frequency and number of transactions occurring during the preceding 12 month period.

(14) The term hearing means any hearing held for the granting, denial, revocation, or suspension of a registration pursuant to sections 303, 304, and 1008 of the Act (21 U.S.C. 823, 824 and 958).

(15) The term international transaction means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.
(16) The term **jurisdiction of the United States** means the customs territory of the United States, the Virgin Islands, the Canal Zone, Guam, American Samoa, and the Trust Territories of the Pacific Islands.

(17) The term **listed chemical** means any List I chemical or List II chemical.

(18) The term **List I chemical** means a chemical specifically designated by the Administrator in §1310.02(a) of this chapter that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act and is important to the manufacture of a controlled substance.

(19) The term **List II chemical** means a chemical, other than a List I chemical, specifically designated by the Administrator in §1310.02(b) of this chapter that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act.

(20) The term **name** means the official name, common or usual name, chemical name, or brand name of a substance.

(21) The term **person** includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(22) The term **readily retrievable** means that certain records are kept by automatic data processing systems or other electronic or mechanized record-keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

(23) The terms **register** and **registration** refer only to registration required and permitted by sections 303 or 1007 of the Act (21 U.S.C. 823 or 957).

(24) The term **registrant** means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

(25) The term **regular customer** means a person with whom the regulated person has an established business relationship for a specified listed chemical or chemicals that has been reported to the Administration subject to the criteria established in §1300.02(b)(12).

(26) The term **regular importer** means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Administrator.

(27) The term **regulated person** means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, tableting machine, or encapsulating machine.

(28) The term **regulated transaction** means:

(i) A distribution, receipt, sale, importation, or exportation of a listed chemical, or an international transaction involving shipment of a listed chemical, or if the Administrator establishes a threshold amount for a specific listed chemical, a threshold amount as determined by the Administrator, which includes a cumulative threshold amount for multiple transactions, of a listed chemical, except that such term does not include:

(A) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person;

(B) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with parts 1309, 1310, and 1313 of this chapter;

(C) Any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Administrator as excluded from this definition as unnecessary for enforcement of the Act.
(D) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act unless—

(i) The drug contains ephedrine or its salts, optical isomers, or salts of optical isomers; or

(ii) The Administrator has determined pursuant to the criteria in 1310.10 that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(2) The quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical.

(E) Any transaction in a chemical mixture listed in §1310.13 of this chapter.

(ii) A distribution, importation, or exportation of a tableting machine or encapsulating machine except that such term does not include a domestic lawful distribution in the usual course of business between agents and employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person.

(29) The term retail distributor means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to drug products containing pseudoephedrine, phenylpropanolamine, or ephedrine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. For the purposes of this paragraph, sale for personal use means the distribution of below-threshold quantities in a single transaction to an individual for legitimate medical use. Also for the purposes of this paragraph, a grocery store is an entity within Standard Industrial Classification (SIC) code 5411, a general merchandise store is an entity within SIC codes 5300 through 5399 and 5499, and a drug store is an entity within SIC code 5912.

(30) The term tableting machine means any manual, semi-automatic, or fully automatic equipment which may be used for the compaction or molding of powdered or granular solids, or semi-solid material, to produce coherent solid tablets.

final order; extension of registration pending final order.

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General Information

§ 1301.01 Scope of this part 1301.

Procedures governing the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances pursuant to sections 301–304 and 1007–1008 of the Act (21 U.S.C. 821–824 and 957–958) are set forth generally by those sections and specifically by the sections of this part.


§ 1301.02 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.


§ 1301.03 Information; special instructions.

Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005.


Registration

§ 1301.11 Persons required to register.

(a) Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§1301.22–1301.26. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

(b) [Reserved]


§ 1301.12 Separate registrations for separate locations.

(a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.
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(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

1. A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of subsection 302(c)(2) or subsection 1007(b)(1)(B) of the Act (21 U.S.C. 822(c)(2) or 957(b)(1)(B));

2. An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders; and

3. An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

4. A freight forwarding facility, as defined in §1300.01 of this part, provided that the distributing registrant operating the facility has submitted written notice of intent to operate the facility by registered mail, return receipt requested (or other suitable means of documented delivery) and such notice has been approved. The notice shall be submitted to the Special Agent in Charge of the Administration’s offices in both the area in which the facility is located and each area in which the distributing registrant maintains a registered location that will transfer controlled substances through the facility. The notice shall detail what state licensing requirements apply to the facility and the registrant’s actions to comply with any such requirements. The Special Agent in Charge of the DEA Office in the area where the freight forwarding facility will be operated will provide written notice of approval or disapproval to the person within thirty days after confirmed receipt of the notice. Registrants that are currently operating freight forwarding facilities under a memorandum of understanding with the Administration must provide notice as required by this section no later than September 18, 2000 and receive written approval from the Special Agent in Charge of the DEA Office in the area in which the freight forwarding facility is operated in order to continue operation of the facility.


§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person.

(b) Any person who is registered may apply to be reregistered not more than 60 days before the expiration date of his/her registration, except that a bulk manufacturer of Schedule I or II controlled substances or an importer of Schedule I or II controlled substances may apply to be reregistered no more than 120 days before the expiration date of their registration.

(c) At the time a manufacturer, distributor, researcher, analytical lab, importer, exporter or narcotic treatment program is first registered, that business activity shall be assigned to one of twelve groups, which shall correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the
last date of the month designated for that group. In assigning any of the above business activities to a group, the Administration may select a group the expiration date of which is less than one year from the date such business activity was registered. If the business activity is assigned to a group which has an expiration date less than three months from the date of which the business activity is registered, the registration shall expire on the expiration date following the date on which the business activity is registered.

(d) At the time a retail pharmacy, hospital/clinic, practitioner or teaching institution is first registered, that business activity shall be assigned to one of twelve groups, which shall correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the last day of the month designated for that group. In assigning any of the above business activities to a group, the Administration may select a group the expiration date of which is less than three months from the date such business activity was registered. After the initial registration period, the registration shall expire 36 months from the initial expiration date.

(e) Any person who is required to be registered and who is not so registered, shall make application for registration for one of the following groups of controlled substances activities, which are deemed to be independent of each other. Application for each registration shall be made on the indicated form, and shall be accompanied by the indicated fee. Fee payments shall be made in the form of a personal, certified, or cashier’s check or money order made payable to the “Drug Enforcement Administration”. The application fees are not refundable. Any person, when registered to engage in the activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described without obtaining a registration to engage in such coincident activities, provided that, unless specifically exempted, he/she complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities. Any person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this paragraph under coincident activities. A single registration to engage in any group of independent activities listed below may include one or more controlled substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in Schedule I may conduct research with any substances listed in Schedule I for which he/she has filed and had approved a research protocol.

<table>
<thead>
<tr>
<th>Business activity</th>
<th>Controlled substances</th>
<th>DEA application forms</th>
<th>Application fee (dollars)</th>
<th>Registration period (years)</th>
<th>Coincident activities allowed</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) Manufacturing</td>
<td>Schedules I through V</td>
<td>New—225</td>
<td>875</td>
<td>1</td>
<td>Schedules I through V: May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered. Schedules II through V: May conduct chemical analysis and preclinical research (including quality control analysis) with substances listed in those schedules for which authorization as a manufacturer was issued.</td>
</tr>
<tr>
<td></td>
<td>Renewal—225a</td>
<td></td>
<td>875</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(ii) Distributing</td>
<td>Schedules I through V</td>
<td>New—225</td>
<td>438</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Renewal—225a</td>
<td></td>
<td>438</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Business activity</td>
<td>Controlled substances</td>
<td>DEA application forms</td>
<td>Application fee (dollars)</td>
<td>Registration period (years)</td>
<td>Coincident activities allowed</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
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</tr>
<tr>
<td>(iii) Dispensing or Instructing (includes Practitioner Hospital/Clinic, Retail Pharmacy, Teaching Institution)</td>
<td>Schedules II through V</td>
<td>New—224 Renewal—224a</td>
<td>210</td>
<td>210</td>
<td>3 May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under state statute. A pharmacist may manufacture an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in Schedule II through V in a proportion not exceeding 20 percent of the complete solution, compound, or mixture.</td>
</tr>
<tr>
<td>(iv) Research</td>
<td>Schedule I</td>
<td>New—225 Renewal—225a</td>
<td>70</td>
<td>70</td>
<td>1 A researcher may manufacture or import the basic class of substance or substances for which registration was issued, provided that such manufacture or import is set forth in the protocol required in Section 1301.18 and to distribute such class to persons registered or authorized to conduct research with such class of substance or registered or authorized to conduct chemical analysis with controlled substances.</td>
</tr>
<tr>
<td>(v) Research</td>
<td>Schedules II through V</td>
<td>New—225 Renewal—225a</td>
<td>70</td>
<td>70</td>
<td>1 May conduct chemical analysis with controlled substances in those schedules for which registration was issued; manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration or reregistration and provided that the manufacture is not for the purposes of dosage form development; import such substances for research purposes; distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances, and to persons exempted from registration pursuant to Section 1301.24; and conduct instructional activities with controlled substances.</td>
</tr>
<tr>
<td>(vi) Narcotic Treatment Program (including compounding)</td>
<td>Narcotic Drugs in Schedules II through V</td>
<td>New—363 Renewal—363a</td>
<td>70</td>
<td>70</td>
<td>1</td>
</tr>
<tr>
<td>(vi) Importing</td>
<td>Schedules I through V</td>
<td>New—225 Renewal—225a</td>
<td>438</td>
<td>438</td>
<td>1 May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered.</td>
</tr>
<tr>
<td>(viii) Exporting</td>
<td>Schedules I through V</td>
<td>New—225 Renewal—225a</td>
<td>438</td>
<td>438</td>
<td>1</td>
</tr>
</tbody>
</table>
### Drug Enforcement Administration, Justice

#### § 1301.13

<table>
<thead>
<tr>
<th>Business activity</th>
<th>Controlled substances</th>
<th>DEA application forms</th>
<th>Application fee (dollars)</th>
<th>Registration period (years)</th>
<th>Coincident activities allowed</th>
</tr>
</thead>
<tbody>
<tr>
<td>(ix) Chemical Analysis</td>
<td>Schedules I through V</td>
<td>New—225 Renewal—225a</td>
<td>70 70</td>
<td>1</td>
<td>May manufacture and import controlled substances for analytical or instructional activities; may distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to Section 1301.24; may export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries; and may conduct instructional activities with controlled substances.</td>
</tr>
</tbody>
</table>

(2) DEA Forms 224, 225, and 363 may be obtained at any area office of the Administration or by writing to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005.

(3) DEA Forms 224a, 225a, and 363a will be mailed, as applicable, to each registered person approximately 60 days before the expiration date of his/her registration; if any registered person does not receive such forms within 45 days before the expiration date of his/her registration, he/she must promptly give notice of such fact and request such forms by writing to the Registration Unit of the Administration at the foregoing address.

(f) Each application for registration to handle any basic class of controlled substance listed in Schedule I (except to conduct chemical analysis with such classes), and each application for registration to manufacture a basic class of controlled substance listed in Schedule II shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each basic class to be covered by such registration.

(g) Each application for registration to import or export controlled substances shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each controlled substance whose importation or exportation is to be authorized by such registration.

Registration as an importer or exporter shall not entitle a registrant to import or export any controlled substance not specified in such registration.

(h) Each application for registration to conduct research with any basic class of controlled substance listed in Schedule II shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each such basic class to be manufactured or imported as a coincident activity of that registration. A statement listing the quantity of each such basic class of controlled substance to be imported or manufactured during the registration period for which application is being made shall be included with each such application. For purposes of this paragraph only, manufacturing is defined as the production of a controlled substance by synthesis, extraction or by agricultural/horticultural means.

(i) Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

(j) Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity. An applicant may authorize one or more individuals, who would not otherwise be authorized to
§ 1301.14 Filing of application; acceptance for filing; defective applications.

(a) All applications for registration shall be submitted for filing to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. The appropriate registration fee and any required attachments must accompany the application.

(b) Any person required to obtain more than one registration may submit all applications in one package. Each application must be complete and should not refer to any accompanying application for required information.

(c) Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not generally be accepted for filing. In the case of minor defects as to completeness, the Administrator may accept the application for filing with a request to the applicant for additional information. A defective application will be returned to the applicant within 10 days following its receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time; the Administrator shall accept for filing any application upon resubmission by the applicant, whether complete or not.

(d) Accepting an application for filing does not preclude any subsequent request for additional information pursuant to §1301.15 and has no bearing on whether the application will be granted.


§ 1301.15 Additional information.

The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he/she deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.


§ 1301.16 Amendments to and withdrawal of applications.

(a) An application may be amended or withdrawn without permission of the Administrator at any time before the date on which the applicant receives an order to show cause pursuant to §1301.37. An application may be amended or withdrawn with permission of the Administrator at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.


§ 1301.17 Special procedures for certain applications.

(a) If, at the time of application for registration of a new pharmacy, the pharmacy has been issued a license from the appropriate State licensing agency, the applicant may include with his/her application an affidavit as to the existence of the State license in the following form:
Drug Enforcement Administration, Justice

§ 1301.17

Affidavit for New Pharmacy

I, ___________________________ (Title of officer, official, partner, or other position) of ___________________________ (Corporation, partnership, or sole proprietor), doing business as ___________________________ (Store name) at ___________________________ (Number and Street), (City) (State) (Zip code), hereby certify that said store was issued a pharmacy permit No. ___________________________ by the ___________________________ (Board of Pharmacy or Licensing Agency) of the State of ___________________________ on ___________________________ (Date).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number. I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. 824(a) because of the danger to public health and safety. I further understand that any false information contained in this affidavit may subject me personally to prosecution under 21 U.S.C. 843, the penalties for conviction of which include imprisonment for up to 4 years, a fine of not more than $30,000 or both.

Signature (Person who signs Application for Registration)

______________________________________

County of ___________________________

Subscribed to and sworn before me this ___________________________ day of ___________________________, 19 __________.

Notary Public

(b) Whenever the ownership of a pharmacy is being transferred from one person to another, if the transferee owns at least one other pharmacy licensed in the same State as the one the ownership of which is being transferred, the transferee may apply for registration prior to the date of transfer. The Administrator may register the applicant and authorize him to obtain controlled substances at the time of transfer. Such registration shall not authorize the transferee to dispense controlled substances until the pharmacy has been issued a valid State license. The transferee shall include with his/her application the following affidavit:

Affidavit for Transfer of Pharmacy

I, ___________________________ (Title of officer, official, partner or other position) of ___________________________ (Corporation, partnership, or sole proprietor), doing business as ___________________________ (Store name) hereby certify:

(1) That said company was issued a pharmacy permit No. ___________________________ by the ___________________________ (Board of Pharmacy of Licensing Agency) of the State of ___________________________ and a DEA Registration Number ___________________________ for a pharmacy located at ___________________________ (Number and Street) (City) (State) (Zip Code), and that said company has applied (or will apply on ___________________________ (Date) for a pharmacy permit from the board of pharmacy (or licensing agency) of the State of ___________________________ to do business as ___________________________ (Store name) at ___________________________ (Number and Street) (City) (State) (Zip Code), and

(2) That said company is acquiring the pharmacy business of ___________________________ (Name of Seller) doing business as ___________________________ with DEA Registration Number ___________________________ on or about ___________________________ (Date of Transfer) and that said company has applied (or will apply on ___________________________ (Date) for a pharmacy permit from the board of pharmacy (or licensing agency) of the State of ___________________________ to do business as ___________________________ (Store name) at ___________________________ (Number and Street) (City) (State) (Zip Code).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number.

I understand that if a DEA registration number is issued, the pharmacy may acquire controlled substances but may not dispense them until a pharmacy permit or license is issued by the State board of pharmacy or licensing agency.

I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. 824(a) because of the danger to public health and safety. I further understand that any false information contained in this affidavit may subject me personally to prosecution under 21 U.S.C. 843, the penalties for conviction of which include imprisonment for up to 4 years, a fine of not more than $30,000 or both.

Signature (Person who signs Application for Registration)

______________________________________

County of ___________________________

Subscribed to and sworn before me this ___________________________ day of ___________________________, 19 __________.

Notary Public

(c) The Administrator shall follow the normal procedures for approving an application to verify the statements in the affidavit. If the statements prove to be false, the Administrator may revoke the registration on the basis of section 304(a)(1) of the Act (21 U.S.C. 824(a)(1)) and suspend the registration.
§ 1301.18 21 CFR Ch. II (4–1–01 Edition)

immediately by pending revocation on the basis of section 304(d) of the Act (21 U.S.C. 824(d)). At the same time, the Administrator may seize and place under seal all controlled substances possessed by the applicant under section 304(f) of the Act (21 U.S.C. 824(f)). Intentional misuse of the affidavit procedure may subject the applicant to prosecution for fraud under section 403(a)(4) of the Act (21 U.S.C. 843(a)(4)), and obtaining controlled substances through registration by fraudulent means may subject the applicant to prosecution under section 403(a)(3) of the Act (21 U.S.C. 843(a)(3)). The penalties for conviction of either offense include imprisonment for up to 4 years, a fine not exceeding $30,000 or both.

§ 1301.18 Research protocols.

(a) A protocol to conduct research with controlled substances listed in Schedule I shall be in the following form and contain the following information where applicable:

(1) Investigator:
   (i) Name, address, and DEA registration number; if any.
   (ii) Institutional affiliation.
   (iii) Qualifications, including a curriculum vitae and an appropriate bibliography (list of publications).

(2) Research project:
   (i) Title of project.
   (ii) Statement of the purpose.
   (iii) Name of the controlled substances or substances involved and the amount of each needed.
   (iv) Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.
   (v) Location where the research will be conducted.
   (vi) Statement of the security provisions for storing the controlled substances (in accordance with §1301.75) and for dispensing the controlled substances in order to prevent diversion.
   (vii) If the investigator desires to manufacture or import any controlled substance listed in paragraph (a)(2)(iii) of this section, a statement of the quantity to be manufactured or imported and the sources of the chemicals to be used or the substance to be imported.

(3) Authority:
   (i) Institutional approval.
   (ii) Approval of a Human Research Committee for human studies.
   (iii) Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (number).
   (iv) Indication of an approved funded grant (number), if any.

(b) In the case of a clinical investigation with controlled substances listed in Schedule I, the applicant shall submit three copies of a Notice of Claimed Investigational Exemption for a New Drug (IND) together with a statement of the security provisions (as prescribed in paragraph (a)(2)(vi) of this section for a research protocol) to, and have such submission approved by, the Food and Drug Administration as required in 21 U.S.C. 355(i) and §130.3 of this title. Submission of this Notice and statement to the Food and Drug Administration shall be in lieu of a research protocol to the Administration as required in paragraph (a) of this section. The applicant, when applying for registration with the Administration, shall indicate that such notice has been submitted to the Food and Drug Administration by submitting to the Administration with his/her DEA Form 225 three copies of the following certificate:

I hereby certify that on
(Date), pursuant to 21 U.S.C. 355(i) and 21 CFR 130.3, I, (Name and Address of IND Sponsor) submitted a Notice of Claimed Investigational Exemption for a New Drug (IND) to the Food and Drug Administration for:

(Name of Investigational Drug).

(Date)

(Signature of Applicant).

(c) In the event that the registrant desires to increase the quantity of a controlled substance used for an approved research project, he/she shall submit a request to the Registration Unit, Drug Enforcement Administration, Post Office Box 28083, Central Station, Washington, DC 20005, by registered mail, return receipt requested. The request shall contain the following...
information: DEA registration number; name of the controlled substance or substances and the quantity of each authorized in the approved protocol; and the additional quantity of each desired. Upon return of the receipt, the registrant shall be authorized to purchase the additional quantity of the controlled substance or substances specified in the request. The Administration shall review the letter and forward it to the Food and Drug Administration together with the Administration comments. The Food and Drug Administration shall approve or deny the request as an amendment to the protocol and so notify the registrant. Approval of the letter by the Food and Drug Administration shall authorize the registrant to use the additional quantity of the controlled substance in the research project.

(d) In the event the registrant desires to conduct research beyond the variations provided in the registrant's approved protocol (excluding any increase in the quantity of the controlled substance requested for his/her research project as outlined in paragraph (c) of this section), he/she shall submit three copies of a supplemental protocol in accordance with paragraph (a) of this section describing the new research and omitting information in the supplemental protocol which has been stated in the original protocol. Supplemental protocols shall be processed and approved or denied in the same manner as original research protocols.


§ 1301.22 Exemption of agents and employees; affiliated practitioners.

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his/her business or employment.

(b) An individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner) registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself.

(c) An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that:

(1) Such dispensing, administering or prescribing is done in the usual course of his/her professional practice;
§ 1301.23 Exemption of certain military and other personnel.

(a) The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service, or Bureau of Prisons who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of his/her official duties. Such officials shall follow procedures set forth in part 1306 of this chapter regarding prescriptions, but shall state the branch of service or agency (e.g., “U.S. Army” or “Public Health Service”) and the service identification number of the issuing official in lieu of the registration number required on prescription forms. The service identification number for a Public Health Service employee is his/her Social Security identification number.

(b) The requirement of registration is waived for any official or agency of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, or Public Health Service who or which is authorized to import or export controlled substances in the course of his/her official duties.

(c) If any official exempted by this section also engages as a private individual in any activity or group of activities for which registration is required, such official shall obtain a registration for such private activities.


§ 1301.24 Exemption of law enforcement officials.

(a) The requirement of registration is waived for the following persons in the circumstances described in this section:

(1) Any officer or employee of the Administration, any officer of the U.S. Customs Service, any officer or employee of the United States Food and Drug Administration, and any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to controlled substances, drugs or customs, and is duly authorized to possess or to import or export controlled substances in the course of his/her official duties; and

(2) Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his/her official duties.

(b) Any official exempted by this section may, when acting in the course of his/her official duties, procure any controlled substance in the course of an inspection, in accordance with §1316.03(d) of this chapter, or in the course of any criminal investigation involving the person from whom the substance was procured, and may possess any controlled substance and distribute any such substance to any other official who is also exempted by this section and acting in the course of his/her official duties.

(c) In order to enable law enforcement agency laboratories, including
§ 1301.25 Registration regarding ocean vessels, aircraft, and other entities.

(a) If acquired by and dispensed under the general supervision of a medical officer described in paragraph (b) of this section, or the master or first officer of the vessel under the circumstances described in paragraph (d) of this section, controlled substances may be held for stocking, be maintained in, and dispensed from medicine chests, first aid packets, or dispensaries:

(1) On board any vessel engaged in international trade or in trade between ports of the United States and any merchant vessel belonging to the U.S. Government;

(2) On board any aircraft operated by an air carrier under a certificate of permit issued pursuant to the Federal Aviation Act of 1958 (49 U.S.C. 1301); and

(3) In any other entity of fixed or transient location approved by the Administrator as appropriate for application of this section (e.g., emergency kits at field sites of an industrial firm).

(b) A medical officer shall be:

(1) Licensed in a state as a physician;

(2) Employed by the owner or operator of the vessel, aircraft or other entity; and

(3) Registered under the Act at either of the following locations:

(i) The principal office of the owner or operator of the vessel, aircraft or other entity or

(ii) At any other location provided that the name, address, registration number and expiration date as they appear on his/her Certificate of Registration (DEA Form 223) for this location are maintained for inspection at said principal office in a readily retrievable manner.

(c) A registered medical officer may serve as medical officer for more than one vessel, aircraft, or other entity under a single registration, unless he/she serves as medical officer for more than one owner or operator, in which case he/she shall either maintain a separate registration at the location of the principal office of each such owner or operator or utilize one or more registrations pursuant to paragraph (b)(3)(ii) of this section.

(d) If no medical officer is employed by the owner or operator of a vessel, or in the event such medical officer is not accessible and the acquisition of controlled substances is required, the master or first officer of the vessel, who shall not be registered under the Act, may purchase controlled substances from a registered manufacturer or distributor, or from an authorized pharmacy as described in paragraph (f) of this section, by following the procedure outlined below:

(1) The master or first officer of the vessel must personally appear at the vendor’s place of business, present proper identification (e.g., Seaman’s photographic identification card) and a written requisition for the controlled substances.

(2) The written requisition must be on the vessel’s official stationery or purchase order form and must include the name and address of the vendor, the name of the controlled substance, description of the controlled substance, etc.
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(dosage form, strength and number or volume per container) number of containers ordered, the name of the vessel, the vessel’s official number and country of registry, the owner or operator of the vessel, the port at which the vessel is located, signature of the vessel’s officer who is ordering the controlled substances and the date of the requisition.

(3) The vendor may, after verifying the identification of the vessel’s officer requisitioning the controlled substances, deliver the control substances to that officer. The transaction shall be documented, in triplicate, on a record of sale in a format similar to that outlined in paragraph (d)(4) of this section. The vessel’s requisition shall be attached to copy 1 of the record of sale and filed with the controlled substances records of the vendor, copy 2 of the record of sale shall be furnished to the officer of the vessel and retained aboard the vessel, copy 3 of the record of sale shall be forwarded to the nearest DEA Division Office within 15 days after the end of the month in which the sale is made.

(4) The vendor’s record of sale should be similar to, and must include all the information contained in, the below listed format.

SALE OF CONTROLLED SUBSTANCES TO VESSELS

<table>
<thead>
<tr>
<th>Line No.</th>
<th>Number of packages ordered</th>
<th>Size of packages</th>
<th>Name of product</th>
<th>Packages distributed</th>
<th>Date distributed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Footnote: Line numbers may be continued according to needs of the vendor.

Number of lines completed __________

Name of vessel __________________________

Vessel’s official number __________________

Owner or operator of the vessel ________________

Name and title of vessel’s officer who presented the requisition ________________

Signature of vessel’s officer who presented the requisition ________________

(e) Any medical officer described in paragraph (b) of this section shall, in addition to complying with all requirements and duties prescribed for registrants generally, prepare an annual report as of the date on which his/her registration expires, which shall give in detail an accounting for each vessel, aircraft, or other entity, and a summary accounting for all vessels, aircraft, or other entities under his/her supervision for all controlled substances purchased, dispensed or disposed of during the year. The medical officer shall maintain this report with other records required to be kept under the Act and, upon request, deliver a copy of the report to the Administration. The medical officer need not be present when controlled substances are dispensed, if the person who actually dispensed the controlled substances is responsible to the medical officer to justify his/her actions.

(f) Any registered pharmacy that wishes to distribute controlled substances pursuant to this section shall be authorized to do so, provided:

(1) The registered pharmacy notifies the nearest Division Office of the Administration of its intention to so distribute controlled substances prior to the initiation of such activity. This notification shall be by registered mail and shall contain the name, address, and registration number of the pharmacy as well as the date upon which such activity will commence; and

(2) Such activity is authorized by state law; and

(3) The total number of dosage units of all controlled substances distributed by the pharmacy during any calendar year in which the pharmacy is registered to dispense does not exceed the limitations imposed upon such distribution by §1307.11(a)(4) and (b) of this chapter.

(g) Owners or operators of vessels, aircraft, or other entities described in this section shall not be deemed to possess or dispense any controlled substance acquired, stored and dispensed
§ 1301.32 Action on applications for research in Schedule I substances.

(a) In the case of an application for registration to conduct research with controlled substances listed in Schedule I, the Administrator shall process the application and protocol and forward a copy of each to the Secretary of Health and Human Services (Secretary) within 7 days after receipt. The Secretary shall determine the qualifications and competency of the applicant, as well as the merits of the protocol (and shall notify the Administrator of his/her determination) within 21 days after receipt of the application and complete protocol, except that in the case of a clinical investigation, the Secretary shall have 30 days to make such determination and notify the Administrator. The Secretary, in determining the merits of the protocol, shall consult with the Administrator as to

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§ 1301.33 Application for bulk manufacture of Schedule I and II substances.

(a) In the case of an application for registration or reregistration to manufacture in bulk a basic class of controlled substance listed in Schedule I or II, the Administrator shall, upon the filing of such application, publish in the Federal Register a notice naming the applicant and stating that such applicant has applied to be registered as a bulk manufacturer of a basic class of narcotic or nonnarcotic controlled substance, which class shall be identified. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of that basic class and to any other applicant therefor. Any such person may, within 60 days from the date of publication of the notice in the Federal Register, file with the Administrator written comments on or objections to the issuance of the proposed registration.

(b) In order to provide adequate competition, the Administrator shall not be required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply.

(c) This section shall not apply to the manufacture of basic classes of controlled substances listed in Schedules I or II as an incident to research or chemical analysis as authorized in §1301.13(e)(1).


§ 1301.34 Application for importation of Schedule I and II substances.

(a) In the case of an application for registration or reregistration to import a controlled substance listed in Schedule I or II, under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)), the Administrator shall, upon the filing of such application, publish in the Federal Register a notice naming the applicant and stating that such applicant has applied to be registered as an importer of a Schedule I or II controlled substance, which substance shall be identified. A copy of said notice shall be mailed simultaneously to each person registered as a
bulk manufacturer of that controlled substance and to any other applicant therefor. Any such person may, within 30 days from the date of publication of the notice in the Federal Register, file written comments on or objections to the issuance of the proposed registration, and may, at the same time, file a written request for a hearing on the application pursuant to §1301.43. If a hearing is requested, the Administrator shall hold a hearing on the application in accordance with §1301.41. Notice of the hearing shall be published in the Federal Register, and shall be mailed simultaneously to the applicant and to all persons to whom notice of the application was mailed. Any such person may participate in the hearing by filing a notice of appearance in accordance with §1301.43 of this chapter. Notice of the hearing shall contain a summary of all comments and objections filed regarding the application and shall state the time and place for the hearing, which shall not be less than 30 days after the date of publication of such notice in the Federal Register. A hearing pursuant to this section may be consolidated with a hearing held pursuant to §1301.35 or §1301.36 of this part.

(b) The Administrator shall register an applicant to import a controlled substance listed in Schedule I or II if he/she determines that such registration is consistent with the public interest and with U.S. obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

1. Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in Schedule I or II compounded therefrom into other than legitimate medical, scientific research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

2. Compliance with applicable State and local law;

3. Promotion of technical advances in the art of manufacturing these substances and the development of new substances;

4. Prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

5. Past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion;

6. That the applicant will be permitted to import only:

   (i) Such amounts of crude opium, poppy straw, concentrate of poppy straw, and coca leaves as the Administrator finds to be necessary to provide for medical, scientific, or other legitimate purposes; or

   (ii) Such amounts of any controlled substances listed in Schedule I or II as the Administrator shall find to be necessary to provide for the medical, scientific, or other legitimate needs of the United States during an emergency in which domestic supplies of such substances are found by the Administrator to be inadequate; or

   (iii) Such amounts of any controlled substance listed in Schedule I or II as the Administrator shall find to be necessary for scientific, analytical or research uses; and

7. Such other factors as may be relevant to and consistent with the public health and safety.

(c) In determining whether the applicant can and will maintain effective controls against diversion within the meaning of paragraph (b) of this section, the Administrator shall consider among other factors:

1. Compliance with the security requirements set forth in §§1301.71–1301.76; and
§ 1301.35 Certificate of registration; denial of registration.

(a) The Administrator shall issue a Certificate of Registration (DEA Form 223) to an applicant if the issuance of registration or reregistration is required under the applicable provisions of sections 303 or 1008 of the Act (21 U.S.C. 823 and 958). In the event that the issuance of registration or reregistration is not required, the Administrator shall deny the application. Before denying any application, the Administrator shall issue an order to show cause pursuant to §1301.37 and, if requested by the applicant, shall hold a hearing on the application pursuant to §1301.41.

(b) If in response to a show cause order a hearing is requested by an applicant for registration or reregistration to manufacture in bulk a basic class of controlled substance listed in Schedule I or II, notice that a hearing has been requested shall be published in the FEDERAL REGISTER and shall be mailed simultaneously to the applicant and to all persons to whom notice of the application was mailed. Any person entitled to file comments or objections to the issuance of the proposed registration pursuant to §1301.33(a) may participate in the hearing by filing notice of appearance in accordance with §1301.43. Such persons shall have 30 days to file a notice of appearance after the date of publication of the notice of a request for a hearing in the FEDERAL REGISTER.

(c) The Certificate of Registration (DEA Form 223) shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the schedules and/or Administration Controlled Substances Code Number (as set forth in part 1308 of this chapter) of the controlled substances which the registrant is authorized to handle, the amount of fee paid (or exemption), and the expiration date of the registration. The registrant shall maintain the certificate of registration at the registered location in a readily retrievable manner.

(d) In determining whether competition among the domestic manufacturers of a controlled substance is adequate within the meaning of paragraphs (b)(1) and (b)(6)(iii) of this section, as well as section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)), the Administrator shall consider:

(1) The extent of price rigidity in the light of changes in:
   (i) raw materials and other costs and
   (ii) conditions of supply and demand;
(2) The extent of service and quality competition among the domestic manufacturers for shares of the domestic market including:
   (i) Shifts in market shares and
   (ii) Shifts in individual customers among domestic manufacturers;
(3) The existence of substantial differentials between domestic prices and the higher of prices generally prevailing in foreign markets or the prices at which the applicant for registration to import is committed to undertake to provide such products in the domestic market in conformity with the Act. In determining the existence of substantial differentials hereunder, appropriate consideration should be given to any additional costs imposed on domestic manufacturers by the requirements of the Act and such other cost-related and other factors as the Administrator may deem relevant. In no event shall an importer’s offering prices in the United States be considered if they are lower than those prevailing in the foreign market or markets from which the importer is obtaining his/her supply;
(4) The existence of competitive restraints imposed upon domestic manufacturers by governmental regulations; and
(5) Such other factors as may be relevant to the determinations required under this paragraph.

(e) In considering the scope of the domestic market, consideration shall be given to substitute products which are reasonably interchangeable in terms of price, quality and use.

(f) The fact that the number of existing manufacturers is small shall not demonstrate, in and of itself, that adequate competition among them does not exist.
§ 1301.36 Suspension or revocation of registration; suspension of registration pending final order; extension of registration pending final order.

(a) For any registration issued under section 303 of the Act (21 U.S.C. 823), the Administrator may:

(1) Suspend the registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)) for any period of time.

(2) Revoke the registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)).

(b) For any registration issued under section 1008 of the Act (21 U.S.C. 958), the Administrator may:

(1) Suspend the registration pursuant to section 1008(d) of the Act (21 U.S.C. 958(d)) for any period of time.

(2) Revoke the registration pursuant to section 1008(d) of the Act (21 U.S.C. 958(d)) if he/she determines that such registration is inconsistent with the public interest as defined in section 1008 or with the United States obligations under international treaties, conventions, or protocols in effect on October 12, 1984.

(c) The Administrator may limit the revocation or suspension of a registration to the particular controlled substance, or substances, with respect to which grounds for revocation or suspension exist.

(d) Before revoking or suspending any registration, the Administrator shall issue an order to show cause pursuant to § 1301.37 and, if requested by the registrant, shall hold a hearing pursuant to § 1301.41.

(e) The Administrator may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where he/she finds that there is an imminent danger to the public health or safety. If the Administrator so suspends, he/she shall serve with the order to show cause pursuant to § 1301.37 an order of immediate suspension which shall contain a statement of his findings regarding the danger to public health or safety.

(f) Upon service of the order of the Administrator suspending or revoking registration, the registrant shall immediately deliver his/her Certificate of Registration, any order forms, and any import or export permits in his/her possession to the nearest office of the Administrator. The suspension or revocation of a registration shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant pursuant to part 1303 of this chapter and any import or export permits issued to the registrant pursuant to part 1312 of this chapter. Also, upon service of the order of the Administrator suspending or revoking registration, the registrant shall, as instructed by the Administrator:

(1) Deliver all controlled substances in his/her possession to the nearest office of the Administration or to authorized agents of the Administration; or

(2) Place all controlled substances in his/her possession under seal as described in sections 304(f) or 1008(d)(6) of the Act (21 U.S.C. 824(f) or 958(d)(6)).

(g) In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension; no fee shall be required to be paid for the new Certificate of Registration. The registrant shall deliver the old Certificate of Registration and, if appropriate, any order forms in his/her possession to the nearest office of the Administration. The suspension or revocation of a registration, when limited to a particular basic class or classes of controlled substances, shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant for such class or classes pursuant to part 1303 of this chapter and any import or export permits issued to the registrant for such class or classes pursuant to part 1312 of this chapter. Also, upon service of the order of the Administrator revoking or suspending registration, the registrant
§ 1301.37 Order to show cause.

(a) If, upon examination of the application for registration from any applicant and other information gathered by the Administration regarding the applicant, the Administrator is unable to make the determinations required by the applicable provisions of section 303 and/or section 1008 of the Act (21 U.S.C. 823 and 958) to register the applicant, the Administrator shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information gathered by the Administration regarding any registrant, the Administrator determines that the registration of such registrant is subject to suspension or revocation pursuant to section 304 or section 1008 of the Act (21 U.S.C. 824 and 958), the Administrator shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the Administrator at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant must, if he/she desires a hearing, file a request for a hearing pursuant to §1301.41. If a hearing is requested, the Administrator shall hold a hearing at the time and place stated in the order, pursuant to §1301.41.

(e) When authorized by the Administrator, any agent of the Administration may serve the order to show cause.

§ 1301.37 Order to show cause.

(a) If, upon examination of the application for registration from any applicant and other information gathered by the Administration regarding the applicant, the Administrator is unable to make the determinations required by the applicable provisions of section 303 and/or section 1008 of the Act (21 U.S.C. 823 and 958) to register the applicant, the Administrator shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information gathered by the Administration regarding any registrant, the Administrator determines that the registration of such registrant is subject to suspension or revocation pursuant to section 304 or section 1008 of the Act (21 U.S.C. 824 and 958), the Administrator shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the Administrator at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant must, if he/she desires a hearing, file a request for a hearing pursuant to §1301.41. If a hearing is requested, the Administrator shall hold a hearing at the time and place stated in the order, pursuant to §1301.41.

(e) When authorized by the Administrator, any agent of the Administration may serve the order to show cause.
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§ 1301.44 Burden of proof.

(a) At any hearing on an application to manufacture any controlled substance listed in Schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to section 303(a) of the Act (21 U.S.C. 823(a)) are satisfied. Any other person participating in the hearing pursuant to §1301.35(b) shall have the burden of proving any propositions of fact or law asserted by such person in the hearing.

(b) At any hearing on the granting or denial of an application to conduct a narcotic treatment program or as a compendium, the applicant shall have the burden of proving

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that the requirements for each registration pursuant to section 303(g) of the Act (21 U.S.C. 823(g)) are satisfied.

(c) At any hearing on the granting or denial of an application to be registered to import or export any controlled substance listed in Schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to sections 1008(a) and (d) of the Act (21 U.S.C. 823 or 958(a) and (d)) are satisfied. Any other person participating in the hearing pursuant to §1301.34 shall have the burden of proving any propositions of fact or law asserted by him/her in the hearings.

(d) At any other hearing for the denial of a registration, the Administration shall have the burden of proving that the requirements for such registration pursuant to section 303 or section 1008(c) and (d) of the Act (21 U.S.C. 823 or 958(c) and (d)) are not satisfied.

(e) At any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to section 304(a) or section 1008(d) of the Act (21 U.S.C. 824(a) or 958(d)) are satisfied.


§1301.45 Time and place of hearing.

The hearing will commence at the place and time designated in the order to show cause or notice of hearing published in the FEDERAL REGISTER (unless expedited pursuant to §1301.36(h)) but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.


§1301.46 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his/her order on the granting, denial, revocation, or suspension of registration. In the event that an application for registration to import or to manufacture in bulk a basic class of any controlled substance listed in Schedule I or II is granted, or any application for registration is denied, or any registration is revoked or suspended, the order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. The Administrator shall serve one copy of his/her order upon each party in the hearing.


MODIFICATION, TRANSFER AND TERMINATION OF REGISTRATION

§1301.51 Modification in registration.

Any registrant may apply to modify his/her registration to authorize the handling of additional controlled substances or to change his/her name or address, by submitting a letter of request to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. The letter shall contain the registrant’s name, address, and registration number as printed on the certificate of registration, and the substances and/or schedules to be added to his/her registration or the new name or address and shall be signed in accordance with §1301.13(j). If the registrant is seeking to handle additional controlled substances listed in Schedule I for the purpose of research or instructional activities, he/she shall attach three copies of a research protocol describing each research project involving the additional substances, or two copies of a statement describing the nature, extent, and duration of such instructional activities, as appropriate. No fee shall be required to be paid for the modification. The request for modification shall be handled in the same manner as an application for registration. If the modification in registration is approved, the Administrator shall issue a new certificate of registration (DEA Form 223) to the registrant, who shall maintain it with the old certificate of registration until expiration.

§ 1301.52 Termination of registration; transfer of registration; distribution upon discontinuance of business.

(a) Except as provided in paragraph (b) of this section, the registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues business or professional practice. Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Administrator promptly of such fact.

(b) No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Administration may specifically designate and then only pursuant to written consent. Any person seeking authority to transfer a registration shall submit a written request, providing full details regarding the proposed transfer of registration, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(c) Any registrant desiring to discontinue business activities altogether or with respect to controlled substances (without transferring such business activities to another person) shall return for cancellation his/her certificate of registration, and any unexecuted order forms in his/her possession, to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. Any controlled substances in his/her possession may be disposed of in accordance with §1307.21 of this chapter.

(d) Any registrant desiring to discontinue business activities altogether or with respect to controlled substances (by transferring such business activities to another person) shall submit in person or by registered or certified mail, return receipt requested, to the Special Agent in Charge in his/her area, at least 14 days in advance of the date of the proposed transfer (unless the Special Agent in Charge waives this time limitation in individual instances), the following information:

1. The name, address, registration number, and authorized business activity of the person discontinuing the business (registrant-transferor);

2. The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee);

3. Whether the business activities will be continued at the location registered by the person discontinuing business, or moved to another location (if the latter, the address of the new location should be listed);

4. Whether the registrant-transferor has a quota to manufacture or procure any controlled substance listed in Schedule I or II (if so, the basic class or class of the substance should be indicated); and

5. The date on which the transfer of controlled substances will occur.

(e) Unless the registrant-transferor is informed by the Special Agent in Charge, before the date on which the transfer was stated to occur, that the transfer may not occur, the registrant-transferor may distribute (without being registered to distribute) controlled substances in his/her possession to the registrant-transferee in accordance with the following:

1. On the date of transfer of the controlled substances, a complete inventory of all controlled substances being transferred shall be taken in accordance with §1304.11 of this chapter. This inventory shall serve as the final inventory of the registrant-transferor and the initial inventory of the registrant-transferee, and a copy of the inventory shall be included in the records of each person. It shall not be necessary to file a copy of the inventory with the Administration unless requested by the Special Agent in Charge. Transfers of any substances listed in Schedule I or II shall require the use of order forms in accordance with part 1305 of this chapter.

2. On the date of transfer of the controlled substances, all records required to be kept by the registrant-transferor with reference to the controlled substances being transferred, under part 1304 of this chapter, shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.
(3) In the case of registrants required to make reports pursuant to part 1304 of this chapter, a report marked “Final” will be prepared and submitted by the registrant-transferor showing the disposition of all the controlled substances for which a report is required; no additional report will be required from him, if no further transactions involving controlled substances are consummated by him. The initial report of the registrant-transferee shall account for transactions beginning with the day next succeeding the date of discontinuance or transfer of business by the transferor-registrant and the substances transferred to him shall be reported as receipts in his/her initial report.


SECURITY REQUIREMENTS

§ 1301.71 Security requirements generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in §§ 1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in §§ 1301.72–1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:

(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);

(2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);

(3) The quantity of controlled substances handled;

(4) The location of the premises and the relationship such location bears on security needs;

(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;

(7) The type of closures on vaults, safes, and secure enclosures;

(8) The adequacy of key control systems and/or combination lock control systems;

(9) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;

(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) The adequacy of supervision over employees having access to manufacturing and storage areas;

(12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;

(13) The availability of local police protection or of the registrant’s or applicant’s security personnel, and;

(14) The adequacy of the registrant’s or applicant’s system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a noncontrolled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in §§ 1301.72-
§ 1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

(a) Schedules I and II. Raw material, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedule I or II (except GHB that is manufactured or distributed in accordance with an exemption under section 505(i) of the FFDCA which shall be subject to the requirements of paragraph (b) of this section) shall be stored in one of the following secured areas:

(1) Where small quantities permit, a safe or steel cabinet;
   (i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;
   (ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and
   (iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve.

(2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system;

(3) A vault constructed after September 1, 1971.
   (i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with ½-inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;
   (ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;
   (iii) Which vault, if operations require it to remain open for frequent access, is equipped with a “day-gate” which is self-closing and self-locking.
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or the equivalent, for use during the hours of operation in which the vault door is open;

(iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

(v) The door of which vault is equipped with contact switches; and

(vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration.

(b) Schedules III, IV and V. Raw material, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV, and V, and GHB when it is manufactured or distributed in accordance with an exemption under section 505(i) of the FFDCA, shall be stored in the following secure storage areas:

(1) A safe or steel cabinet as described in paragraph (a)(1) of this section;

(2) A vault as described in paragraph (a)(2) or (3) of this section equipped with an alarm system as described in paragraph (b)(4)(v) of this section;

(3) A building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications:

(i) Has an electronic alarm system as described in paragraph (b)(4)(v) of this section;

(ii) Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:

(a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;

(b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination;

(4) A cage, located within a building on the premises, meeting the following specifications:

(i) Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:

(a) At least one inch in diameter;

(b) Set in concrete or installed with lag bolts that are pinned or brazed; and

(c) Which are placed no more than ten feet apart with horizontal one and one-half inch reinforcements every sixty inches;

(ii) Having a mesh construction with openings of not more than two and one-half inches across the square,

(iii) Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height;

(iv) Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b)(3)(ii), and

(v) Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond, or to a 24-hour
control station operated by the registrant, or to such other source of protection as the Administrator may approve;

(5) An enclosure of masonry or other material, approved in writing by the Administrator as providing security comparable to a cage;

(6) A building or enclosure within a building which has been inspected and approved by DEA or its predecessor agency, BND, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment has been made by the Special Agent in Charge of DEA for the area in which such building or enclosure is situated;

(7) Such other secure storage areas as may be approved by the Administrator after considering the factors listed in §1301.71(b), (1) through (14);

(8)(i) Schedule III through V controlled substances may be stored with Schedules I and II controlled substances under security measures provided by 21 CFR 1301.72(a);

(ii) Non-controlled drugs, substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by 21 CFR 1301.72(b), provided that permission for such storage of non-controlled items is obtained in advance, in writing, from the Special Agent in Charge of DEA for the area in which such storage area is situated. Any such permission tendered must be upon the Special Agent in Charge’s written determination that such non-segregated storage does not diminish security effectiveness for Schedules III through V controlled substances.

(c) Multiple storage areas. Where several types or classes of controlled substances are handled separately by the registrant or applicant for different purposes (e.g., returned goods, or goods in process), the controlled substances may be stored separately, provided that each storage area complies with the requirements set forth in this section.

(d) Accessibility to storage areas. The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.


EDITORIAL NOTE: For Federal Register citations affecting §1301.72, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.

All manufacturing activities (including processing, packaging and labeling) involving controlled substances listed in any schedule and all activities of compounders shall be conducted in accordance with the following:

(a) All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked, with adequate security for the area or building. If such security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.

(b) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area. “Limited access” may be provided, in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as
§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Field Division Office of the Administration in his area of any theft or significant loss of any controlled substances upon discovery of such theft or loss. The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to §1301.74(e), upon discovery of such theft or loss. The registrant shall also complete DEA Form 106 regarding such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of part 1305 of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term ‘‘customer’’ includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in §1301.72. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible
for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of carfentanil etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substances(s) by contacting the Drug Enforcement Administration.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner.

(j) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

(k) All narcotic treatment programs must comply with standards established by the Secretary of Health and Human Services (after consultation with the Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

(l) DEA may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.


EDITORIAL NOTE: For Federal Register citations affecting §1301.74, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 1301.75 Physical security controls for practitioners.

(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(c) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.

(d) Carfentanil etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.


§ 1301.76 Other security controls for practitioners.

(a) The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term “for cause” means a surrender in lieu of, or as a consequence
§ 1301.77 Security controls for freight forwarding facilities.

(a) All Schedule II–V controlled substances that will be temporarily stored at the freight forwarding facility must be either:

1. stored in a segregated area under constant observation by designated responsible individual(s); or

2. stored in a secured area that meets the requirements of Section 1301.72(b) of this Part. For purposes of this requirement, a facility that may be locked down (i.e., secured against physical entry in a manner consistent with requirements of Section 1301.72(b)(3)(ii) of this part) and has a monitored alarm system or is subject to continuous monitoring by security personnel will be deemed to meet the requirements of Section 1301.72(b)(3) of this Part.

(b) Access to controlled substances must be kept to an absolute minimum number of specifically authorized individuals. Non-authorized individuals may not be present in or pass through controlled substances storage areas without adequate observation provided by an individual authorized in writing by the registrant.

(c) Controlled substances being transferred through a freight forwarding facility must be packed in sealed, unmarked shipping containers.

[65 FR 44678, July 19, 2000; 65 FR 45829, July 25, 2000]

EMPLOYEE SCREENING—NON-PRACTITIONERS

§ 1301.90 Employee screening procedures.

It is the position of DEA that the obtaining of certain information by non-practitioners is vital to fairly assess the likelihood of an employee committing a drug security breach. The need to know this information is a matter of business necessity, essential to overall controlled substances security. In this regard, it is believed that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry. It is, therefore, assumed that the following questions will become a part of an employer’s comprehensive employee screening program:

Question. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses, or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date and sentence.

Question. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details.

Advice. An authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending charges or convictions must be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person must be advised that any false information or omission of information will jeopardize his or her position with respect to employment. The application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person’s qualifications. The maintaining of fair employment practices, the protection of the person’s right of privacy, and the assurance that the results of such inquiries will be

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§ 1301.91 Employee responsibility to report drug diversion.

Reports of drug diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy.

[40 FR 17143, Apr. 17, 1975]

§ 1301.92 Illicit activities by employees.

It is the position of DEA that employees who possess, sell, use or divert controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee’s violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

[40 FR 17143, Apr. 17, 1975]

§ 1301.93 Sources of information for employee checks.

DEA recommends that inquiries concerning employees’ criminal records be made as follows:

Local inquiries. Inquiries should be made by name, date and place of birth, and other identifying information, to local courts and law enforcement agencies for records of pending charges and convictions. Local practice may require such inquiries to be made in person, rather than by mail, and a copy of an authorization from the employee may be required by certain law enforcement agencies. DEA inquiries. Inquiries supplying identifying information should also be furnished to DEA Field Division Offices along with written consent from the concerned individual for a check of DEA files for records of convictions. The Regional check will result in a national check being made by the Field Division Office.

[40 FR 17143, Apr. 17, 1975, as amended at 47 FR 41735, Sept. 22, 1982]

PART 1302—LABELING AND PACKAGING REQUIREMENTS FOR CONTROLLED SUBSTANCES

Sec. 1302.01 Scope of part 1302.
1302.02 Definitions.
1302.03 Symbol required; exceptions.
1302.04 Location and size of symbol on label and labeling.
1302.05 Effective dates of labeling requirements.
1302.06 Sealing of controlled substances.
1302.07 Labeling and packaging requirements for imported and exported substances.


§ 1302.01 Scope of part 1302.

Requirements governing the labeling and packaging of controlled substances pursuant to sections 1305 and 1008(d) of the Act (21 U.S.C. 825 and 958(d)) are set forth generally by those sections and specifically by the sections of this part.


§ 1302.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.


§ 1302.03 Symbol required; exceptions.

(a) Each commercial container of a controlled substance (except for a controlled substance excepted by the Administrator pursuant to §1308.31 of this chapter) shall have printed on the label...
§ 1302.04 Location and size of symbol on label and labeling.

The symbol shall be prominently located on the label or the labeling of the commercial container and/or the panel of the commercial container normally displayed to dispensers of any controlled substance. The symbol on labels shall be clear and large enough to afford easy identification of the schedule of the controlled substance upon inspection of the label.


§ 1302.05 Effective dates of labeling requirements.

All labels on commercial containers of, and all labeling of, a controlled substance which either is transferred to another schedule or is added to any schedule shall comply with the requirements of §1302.03, on or before the effective date established in the final order for the transfer or addition.


§ 1302.06 Sealing of controlled substances.

On each bottle, multiple dose vial, or other commercial container of any controlled substance, there shall be securely affixed to the stopper, cap, lid, covering, or wrapper or such container a seal to disclose upon inspection any tampering or opening of the container.


§ 1302.07 Labeling and packaging requirements for imported and exported substances.

(a) The symbol requirements of §§1302.03–1302.05 apply to every commercial container containing, and to all labeling of, controlled substances imported into the jurisdiction of and/or the customs territory of the United States.

(b) The symbol requirements of §§1302.03–1302.05 do not apply to any commercial containers containing, or any labeling of, a controlled substance intended for export from the jurisdiction of the United States.

(c) The sealing requirements of §1302.06 apply to every bottle, multiple dose vial, or other commercial container of any controlled substance listed in schedule I or II, or any narcotic controlled substance listed in schedule III or IV, imported into, exported from, or intended for export from, the jurisdiction of and/or the customs territory of the United States.

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PART 1303—QUOTAS

GENERAL INFORMATION

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GENERAL INFORMATION

§ 1303.11 Aggregate production and procurement quotas.

(a) The Administrator shall determine the total quantity of each basic class of controlled substance listed in Schedule I or II necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.

(b) In making his determinations, the Administrator shall consider the following factors:

1. Total net disposal of the class by all manufacturers during the current and 2 preceding years;
2. Trends in the national rate of net disposal of the class;
3. Total actual (or estimated) inventories of the class and of all substances manufactured from the class, and trends in inventory accumulation;
4. Projected demand for such class as indicated by procurement quotas requested pursuant to § 1303.12; and
5. Other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

(c) The Administrator shall, on or before May 1 of each year, publish in the FEDERAL REGISTER, general notice of an aggregate production quota for any basic class determined by him under this section. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class. The Administrator shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice the time during which such
§ 1303.12 Procurement quotas.

(a) In order to determine the estimated needs for, and to insure an adequate and uninterrupted supply of, basic classes of controlled substances listed in Schedules I and II (except raw opium being imported by the registrant pursuant to an import permit) the Administrator shall issue procurement quotas authorizing persons to procure and use quantities of each basic class of such substances for the purpose of manufacturing such class into dosage forms or into other substances.

(b) Any person who is registered to manufacture controlled substances listed in any schedule and who desires to use during the next calendar year any basic class of controlled substances listed in Schedule I or II (except raw opium being imported by the registrant pursuant to an import permit) for purposes of manufacturing, shall apply on DEA Form 250 for a procurement quota for such basic class. A separate application must be made for each basic class desired to be procured or used. The applicant shall state whether he intends to manufacture the basic class himself or purchase it from another manufacturer. The applicant shall state separately each purpose for which the basic class is desired, the quantity desired for that purpose during the next calendar year, and the quantities used and estimated to be used, if any, for that purpose during the current and preceding 2 calendar years. If the purpose is to manufacture the basic class into dosage form, the applicant shall state the official name, common or usual name, chemical name, or brand name of that form. If the purpose is to manufacture another substance, the applicant shall state the official name, common or usual name, chemical name, or brand name of the substance, and, if a controlled substance listed in any schedule, the schedule number and Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, of the substance. If the purpose is to manufacture another basic class of controlled substance listed in Schedule I or II, the applicant shall also state the quantity of the other basic class which the applicant has applied to manufacture pursuant to §1303.22 and the quantity of the first basic class necessary to manufacture a specified unit of the second basic class. DEA Form 250 shall be filed on or before April 1 of the year preceding the calendar year for which the procurement quota is being applied. Copies of DEA Form 250 may be obtained from, and shall be filed with, the Drug & Chemical Evaluation Section, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(c) The Administrator shall, on or before July 1 of the year preceding the calendar year during which the quota shall be effective, issue to each qualified applicant a procurement quota authorizing him to procure and use:

1. All quantities of such class necessary to manufacture all quantities of other basic classes of controlled substances listed in Schedules I and II which the applicant is authorized to manufacture pursuant to §1303.22 and the quantity of the first basic class necessary to manufacture a specified unit of the second basic class; and

2. Such other quantities of such class as the applicant has applied to procure and use and are consistent with his past use, his estimated needs,
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§ 1303.13 Adjustments of aggregate production quotas.

(a) The Administrator may at any time increase or reduce the aggregate production quota for a basic class of controlled substance listed in Schedule I or II which he has previously fixed pursuant to §1303.11.

(b) In determining to adjust the aggregate production quota, the Administrator shall consider the following factors:

(1) Changes in the demand for that class, changes in the national rate of net disposal of the class, and changes in the rate of net disposal of the class by registrants holding individual manufacturing quotas for that class;

(2) the total quantity of such class that will be produced.

(d) Any person to whom a procurement quota has been issued may at any time request an adjustment in the quota by applying to the Administrator with a statement showing the need for the adjustment. Such application shall be filed with the Drug & Chemical Evaluation Section, Drug Enforcement Administration, Department of Justice, Washington, DC 20537. The Administrator shall increase or decrease the procurement quota of such person if and to the extent that he finds, after considering the factors enumerated in paragraph (c) of this section and any occurrences since the issuance of the procurement quota, that the need justifies an adjustment.

(e) The following persons need not obtain a procurement quota:

(1) Any person who is registered to manufacture a basic class of controlled substance listed in Schedule I or II and who uses all of the quantity he manufactures in the manufacture of a substance not controlled under the Act;

(2) Any person who is registered or authorized to conduct chemical analysis with controlled substances (for controlled substances to be used in such analysis only); and

(3) Any person who is registered to conduct research with a basic class of controlled substance listed in Schedule I or II and who is authorized to manufacture a quantity of such class pursuant to §1301.13 of this chapter.

(f) Any person to whom a procurement quota has been issued, authorizing that person to procure and use a quantity of a basic class of controlled substances listed in Schedules I or II during the current calendar year, shall, at or before the time of giving an order to another manufacturer requiring the distribution of a quantity of such basic class, certify in writing to such other manufacturer that the quantity of such basic class ordered does not exceed the unused and available procurement quota of such basic class, issued to the person giving the order, for the current calendar year. The written certification shall contain the following: The date of the certification; the name and address of the bulk manufacturer to whom the certification is directed; a reference to the number of the DEA Form 222 to which the certification applies; the name of the person giving the order to which the certification applies; the name of the basic class specified in the DEA Form 222 to which the certification applies; the appropriate schedule within which is listed the basic class specified in the DEA Form 222 to which the certification applies; a statement that the quantity (expressed in grams) of the basic class specified in the DEA Form 222 to which the certification applies does not exceed the unused and available procurement quota of such basic class, issued to the person giving the order, for the current calendar year; and the signature of the individual who signed the DEA Form 222 to which the certification applies.


EDITORIAL NOTE: For Federal Register citations affecting §1303.12, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.
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(2) Whether any increased demand for that class, the national and/or individual rates of net disposal of that class are temporary, short term, or long term;

(3) Whether any increased demand for that class can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota, taking into account production delays and the probability that other individual manufacturing quotas may be suspended pursuant to §1303.24(b);

(4) Whether any decreased demand for that class will result in excessive inventory accumulation by all persons registered to handle that class (including manufacturers, distributors, practitioners, importers, and exporters), notwithstanding the possibility that individual manufacturing quotas may be suspended pursuant to §1303.24(b) or abandoned pursuant to §1303.27;

(5) Other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

(c) The Administrator in the event he determines to increase or reduce the aggregate production quota for a basic class of controlled substance, shall publish in the FEDERAL REGISTER general notice of an adjustment in the aggregate production quota for that class determined by him under this section. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class. The Administrator shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice the time during which such filings may be made. The Administrator may, but shall not be required to, hold a public hearing on one or more issues raised by the comments and objections filed with him. In the event the Administrator decides to hold such a hearing, he shall publish notice of the hearing in the FEDERAL REGISTER, which notice shall summarize the issues to be heard and shall set the time for the hearing, which shall not be less than 10 days after the date of publication of the notice. After consideration of any comments or objections, or after a hearing if one is ordered by the Administrator, the Administrator shall issue and publish in the FEDERAL REGISTER his final order determining the aggregate production for the basic class of controlled substance. The order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. A copy of said order shall be mailed simultaneously to each person registered as a bulk manufacturer of the basic class.


INDIVIDUAL MANUFACTURING QUOTAS

§ 1303.21 Individual manufacturing quotas.

(a) The Administrator shall, on or before July 1 of each year, fix for and issue to each person who is registered to manufacture a basic class of controlled substance listed in Schedule I or II, and who applies for a manufacturing quota, an individual manufacturing quota authorizing that person to manufacture during the next calendar year a quantity of that basic class. Any manufacturing quota fixed and issued by the Administrator shall be subject to his authority to reduce or limit it at a later date pursuant to §1303.24(b) or abandoned pursuant to §1303.27.

(b) No individual manufacturing quota shall be required for registrants listed in §1303.12(e).

§ 1303.22 Procedure for applying for individual manufacturing quotas.

Any person who is registered to manufacture any basic class of controlled substance listed in Schedule I or II and who desires to manufacture a quantity of such class shall apply on DEA Form 189 for a manufacturing quota for such quantity of such class. Copies of DEA Form 189 may be obtained from, and shall be filed (on or before May 1 of the year preceding the calendar year for which the manufacturing quota is being applied) with, the Drug & Chemical Evaluation Section, Drug Enforcement Administration, Department of Justice, Washington, D.C. 20537. A separate application must be made for each basic class desired to be manufactured. The applicant shall state:

(a) The name and Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, of the basic class.
(b) For the basic class in each of the current and preceding 2 calendar years,
(1) The authorized individual manufacturing quota, if any;
(2) The actual or estimated quantity manufactured;
(3) The actual or estimated net disposal;
(4) The actual or estimated inventory allowance pursuant to §1303.24; and
(5) The actual or estimated inventory as of December 31;
(c) For the basic class in the next calendar year,
(1) The desired individual manufacturing quota; and
(2) Any additional factors which the applicant finds relevant to the fixing of his individual manufacturing quota, including the trend of (and recent changes in) his and the national rates of net disposal, his production cycle and current inventory position, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes) and recent unforeseen emergencies such as floods and fires.

§ 1303.23 Procedure for fixing individual manufacturing quotas.

(a) In fixing individual manufacturing quotas for a basic class of controlled substance listed in Schedule I or II, the Administrator shall allocate to each applicant who is currently manufacturing such class a quota equal to 100 percent of the estimated net disposal of that applicant for the next calendar year, adjusted—

(1) By the amount necessary to increase or reduce the estimated inventory of the applicant on December 31 of the current year to his estimated inventory allowance for the next calendar year, pursuant to §1303.24, and
(2) By any other factors which the Administrator deems relevant to the fixing of the individual manufacturing quota of the applicant, including the trend of (and recent changes in) his and the national rates of net disposal, his production cycle and current inventory position, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.
(b) In fixing individual manufacturing quotas for a basic class of controlled substance listed in Schedule I or II, the Administrator shall allocate to each applicant who is not currently manufacturing such class a quota equal to 100 percent of the reasonably estimated net disposal of that applicant for the next calendar year, as determined by the Administrator, adjusted—
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(1) By the amount necessary to provide the applicant his estimated inventory allowance for the next calendar year, pursuant to §1303.24, and

(2) By any other factors which the Administrator deems relevant to the fixing of the individual manufacturing quota of the applicant, including the trend of (and recent changes in) the national rate of net disposal, his production cycle and current inventory position, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires.

(c) The Administrator shall, on or before March 1 of each year, adjust the individual manufacturing quota allocated for that year to each applicant in paragraph (a) of this section by the amount necessary to increase or reduce the actual inventory of the applicant to December 31 of the preceding year to his estimated inventory allowance for the current calendar year, pursuant to §1303.24.


§ 1303.24 Inventory allowance.

(a) For the purpose of determining individual manufacturing quotas pursuant to §1303.23, each registered manufacturer shall be allowed as a part of such quota an amount sufficient to maintain an inventory equal to,

(1) For current manufacturers, 50 percent of his average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) For new manufacturers, 50 percent of his reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(b) During each calendar year each registered manufacturer shall be allowed to maintain an inventory of a basic class not exceeding 65 percent of his estimated net disposal of that class for that year, as determined at the time his quota for that year was determined. At any time the inventory of a basic class held by a manufacturer exceeds 65 percent of his estimated net disposal, his quota for that class is automatically suspended and shall remain suspended until his inventory is less than 60 percent of his estimated net disposal. The Administrator may, upon application and for good cause shown, permit a manufacturer whose quota is, or is likely to be, suspended pursuant to this paragraph to continue manufacturing and to accumulate an inventory in excess of 65 percent of his estimated net disposal, upon such conditions and within such limitations as the Administrator may find necessary or desirable.

(c) If, during a calendar year, a registrant has manufactured the entire quantity of a basic class allocated to him under an individual manufacturing quota, and his inventory of that class is less than 40 percent of his estimated net disposal of that class for that year, the Administrator may, upon application pursuant to §1303.25, increase the quota of such registrant sufficiently to allow restoration of the inventory to 50 percent of the estimated net disposal for that year.


§ 1303.25 Increase in individual manufacturing quotas.

(a) Any registrant who holds an individual manufacturing quota for a basic class of controlled substance listed in Schedule I or II may file with the Administrator an application on Administration Form 189 for an increase in such quota in order for him to meet his estimated net disposal, inventory and other requirements during the remainder of such calendar year.

(b) The Administrator, in passing upon a registrant’s application for an increase in his individual manufacturing quota, shall take into consideration any occurrences since the filing of such registrant’s initial quota application that may require an increased manufacturing rate by such registrant during the balance of the calendar year. In passing upon such application the Administrator may also take into consideration the amount, if any, by which his determination of the total quantity for the basic class of controlled substance to be manufactured exceeds the amount of such quota.
under §1303.11 exceeds the aggregate of all the individual manufacturing quotas for the basic class of controlled substance, and the equitable distribution of such excess among other registrants.

§1303.26 Reduction in individual manufacturing quotas.

The Administrator may at any time reduce an individual manufacturing quota for a basic class of controlled substance listed in Schedule I or II which he has previously fixed in order to prevent the aggregate of the individual manufacturing quotas and import permits outstanding or to be granted from exceeding the aggregate production quota which has been established for that class pursuant of §1303.11, as adjusted pursuant to §1303.13. If a quota assigned to a new manufacturer pursuant to §1303.23(b), or if a quota assigned to any manufacturer is increased pursuant to §1303.24(c), or if an import permit issued to an importer pursuant to part 1312 of this chapter, causes the total quantity of a basic class to be manufactured and imported during the year to exceed the aggregate production quota which has been established for that class pursuant to §1303.11, as adjusted pursuant to §1303.13, the Administrator may proportionately reduce the individual manufacturing quotas and import permits of all other registrants to keep the aggregate production quota within the limits originally established, or, alternatively, the Administrator may reduce the individual manufacturing quota of any registrant whose quota is suspended pursuant to §1303.24(b) or §1303.36 of this chapter, or is abandoned pursuant to §1303.27.

§1303.27 Abandonment of quota.

Any manufacturer assigned an individual manufacturing quota for any basic class pursuant to §1303.23 may at any time abandon his right to manufacture all or any part of such quota by filing with the Drug & Chemical Evaluation Section a written notice of such abandonment, stating the name and Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, of the substance and the amount which he has chosen not to manufacture. The Administrator may, in his discretion, allocate such amount among the other manufacturers in proportion to their respective quotas.

§1303.31 Hearings generally.

(a) In any case where the Administrator shall hold a hearing regarding the determination of an aggregate production quota pursuant to §1303.11(c), or regarding the adjustment of an aggregate production quota pursuant to §1303.13(c), the procedures for such hearing shall be governed generally by the rule making procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by section 306 of the Act (21 U.S.C. 826), by §§1303.32–1303.37, and by the procedures for administrative hearings under the Act set forth in §§1316.41–1316.67 of this chapter.

(b) In any case where the Administrator shall hold a hearing regarding the issuance, adjustment, suspension, or denial of a procurement quota pursuant to §1303.12, or the issuance, adjustment, suspension, or denial of an individual manufacturing quota pursuant to §§1303.21–1303.27, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedures Act (5 U.S.C. 551–559) and specifically by section 306 of the Act (21 U.S.C. 826), by §§1303.32–1303.37, and by the procedures for administrative hearings under the Act set forth in §§1316.41–1316.67 of this chapter.

§ 1303.32 Purpose of hearing.

(a) The Administrator may, in his sole discretion, hold a hearing for the purpose of receiving factual evidence regarding any one or more issues (to be specified by him) involved in the determination or adjustment of any aggregate production quota.

(b) If requested by a person applying for or holding a procurement quota or an individual manufacturing quota, the Administrator shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the issuance, adjustment, suspension, or denial of such quota to such person, but the Administrator need not hold a hearing on the suspension of a quota pursuant to §1301.36 of this chapter separate from a hearing on the suspension of registration pursuant to those sections.

(c) Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.


§ 1303.33 Waiver or modification of rules.

The Administrator or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.


§ 1303.34 Request for hearing or appearance; waiver.

(a) Any applicant or registrant who desires a hearing on the issuance, adjustment, suspension, or denial of his procurement and/or individual manufacturing quota shall, within 30 days after the date of receipt of the issuance, adjustment, or denial of such quota, file with the Administrator a written request for a hearing in the form prescribed in §1316.47 of this chapter. Any interested person who desires a hearing on the determination of an aggregate production quota shall, within the time prescribed in §1303.11(c), file with the Administrator a written request for a hearing in the form prescribed in §1316.47 of this chapter, including in the request a statement of the grounds for a hearing.

(b) Any interested person who desires to participate in a hearing on the determination or adjustment of an aggregate production quota, which hearing is ordered by the Administrator pursuant to §1303.11(c) or §1303.13(c) may do so by filing with the Administrator, within 30 days of the date of publication of notice of the hearing in the Federal Register, a written notice of his intention to participate in such hearing in the form prescribed in §1316.48 of this chapter.

(c) Any person entitled to a hearing or to participate in a hearing pursuant to paragraph (b) of this section, may, within the period permitted for filing a request for a hearing of notice of appearance, file with the Administrator a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(d) If any person entitled to a hearing or to participate in a hearing pursuant to paragraph (b) of this section, fails to file a request for a hearing or notice of appearance, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

(e) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his
§ 1303.37 Final order.
As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his order on the determination or adjustment of the aggregate production quota or on the issuance, adjustment, suspension, or denial of the procurement quota or individual manufacturing quota, as case may be. The order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. The Administrator shall serve one copy of his order upon each party in the hearing.


PART 1304—RECORDS AND REPORTS OF REGISTRANTS

GENERAL INFORMATION

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AUTHORITY: 21 U.S.C. 821, 827, 871(b), 958(e), 965, unless otherwise noted.

§ 1304.01  General Information

§ 1304.01 Scope of part 1304.

Inventory and other records and reports required under section 307 or section 1008(d) of the Act (21 U.S.C. 827 and 958(d)) shall be in accordance with, and contain the information required by, those sections and by the sections of this part.


§ 1304.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.


§ 1304.03 Persons required to keep records and file reports.

(a) Each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section. Any registrant who is authorized to conduct other activities without being registered to conduct those activities, either pursuant to §1301.22(b) of this chapter or pursuant to §§1307.11–1307.15 of this chapter, shall maintain the records and inventories and shall file the reports required by this part for persons registered to conduct such activities. This latter requirement should not be construed as requiring stocks of controlled substances being used in various activities under one registration to be stored separately, nor that separate records are required for each activity. The intent of the Administration is to permit the registrant to keep one set of records which are adapted by the registrant to account for controlled substances used in any activity. Also, the Administration does not wish to acquire separate stocks of the same substance to be purchased and stored for separate activities. Otherwise, there is no advantage gained by permitting several activities under one registration. Thus, when a researcher manufactures a controlled item, he must keep a record of the quantity manufactured; when he distributes a quantity of the item, he must use and keep invoices or order forms to document the transfer; when he imports a substance, he keeps as part of his records the documentation required of an importer; and when substances are used in chemical analysis, he need not keep a record of this because such a record would not be required of him under a registration to do chemical analysis. All of these records may be maintained in one consolidated record system. Similarly, the researcher may store all of his controlled items in one place, and every two years take inventory of all items on hand, regardless of whether the substances were manufactured by him, imported by him, or purchased domestically by him, of whether the substances will be administered to subjects, distributed to other researchers, or destroyed during chemical analysis.

(b) A registered individual practitioner is required to keep records, as described in §1304.04, of controlled substances in Schedules II, III, IV, and V which are dispensed, other than by prescribing or administering in the lawful course of professional practice.

(c) A registered individual practitioner is not required to keep records of controlled substances listed in Schedules II, III, IV and V which are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment of an individual.

(d) A registered individual practitioner is not required to keep records of controlled substances listed in Schedules II, III, IV and V which are administered in the course of maintenance or detoxification treatment of an individual.

(e) Each registered mid-level practitioner shall maintain in a readily retrievable manner those documents required by the state in which he/she practices which describe the conditions and extent of his/her authorization to...
Drug Enforcement Administration, Justice

§ 1304.04 Maintenance of records and inventories.

(a) Every inventory and other records required to be kept under this part shall be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration, except that financial and shipping records (such as invoices and packing slips but not executed order forms subject to §1305.13 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge.

All notifications must include:

(1) The nature of the records to be kept centrally.

(2) The exact location where the records will be kept.

(3) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.

(4) Whether central records will be maintained in a manual, or computer readable form.

must be maintained for a period of two years.

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(b) All registrants that are authorized to maintain a central recordkeeping system shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms, prescriptions and/or inventories which shall be maintained at each registered location.

(2) If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.

(3) The registrant agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a written request from the Administration for such records, and if the Administration chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Administration to inspect such records at the central location upon request by such employees without a warrant of any kind.

(4) In the event that a registrant fails to comply with these conditions, the Special Agent in Charge may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the registrant without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorizations under this paragraph the registrant shall, within the time specified by the Special Agent in Charge, comply with the requirements of this section that all records be kept at the registered location.

(c) Registrants need not notify the Special Agent in Charge or obtain central recordkeeping approval in order to maintain records on an in-house computer system.

(d) ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Request for central reporting identifiers will be submitted to: ARCOS Unit, P.O. Box 28293, Central Station, Washington, DC 20005.

(e) All central recordkeeping permits previously issued by the Administration expired September 30, 1980.

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounding pharmacy shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(g) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (f) of this section.

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from the ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and

(i) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file.

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from the ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file.

(j) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file.

(j) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file.

(j) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file.

(j) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file.

(j) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file.
§ 1304.11 Inventory requirements.

(a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be “on hand” if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b) Initial inventory date. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

(d) Inventory date for newly controlled substances. On the effective date of a rule by the Administrator pursuant to §§ 1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.

(e) Inventories of manufacturers, distributors, dispensers, researchers, importers, exporters and chemical analysts. Each person registered or authorized (by §1301.13 or §§1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export, conduct research or chemical analysis with controlled substances and required to keep records pursuant to §1304.03 shall include in the inventory the information listed below.

(1) Inventories of manufacturers. Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:
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(i) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:

(A) The name of the substance and
(B) The total quantity of the substance to the nearest metric unit weight consistent with unit size.

(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:

(A) The name of the substance;
(B) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and
(C) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.

(iii) For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;
(B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter); and
(C) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and
(D) The number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials).

(iv) For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

(A) The name of the substance;
(B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and
(C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

(2) Inventories of distributors. Each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section.

(3) Inventories of dispensers and researchers. Each person registered or authorized to dispense or conduct research with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

(i) If the substance is listed in Schedule I or II, make an exact count or measure of the contents, or
(ii) If the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

(4) Inventories of importers and exporters. Each person registered or authorized to import or export controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. Each such person who is also registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

(5) Inventories of chemical analysts. Each person registered or authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section as to substances which have
been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Administration may possess up to 150 grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

(62 FR 13959, Mar. 24, 1997)

CONTINUING RECORDS
§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.

Each person registered or authorized (by § 1301.13(e) or §§ 1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export or conduct research with controlled substances shall maintain records with the information listed below.

(a) Records for manufacturers. Each person registered or authorized to manufacture controlled substances shall maintain records with the following information:

(i) The name of the substance;

(ii) The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

(iii) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;

(iv) The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him/her, including the date, quantity, and import permit or declaration number for each importation;

(v) The quantity used to manufacture the same substance in finished form, including:

(A) The date and batch or other identifying number of each manufacture;

(B) The quantity used in the manufacture;

(C) The finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter);

(D) The number of units of finished form manufactured;

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(E) The quantity used in quality control;
(F) The quantity lost during manufacturing and the causes therefore, if known;
(G) The total quantity of the substance contained in the finished form;
(H) The theoretical and actual yields; and
(I) Such other information as is necessary to account for all controlled substances used in the manufacturing process;
(vi) The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in paragraph (a)(1)(v) of this section;
(vii) The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;
(viii) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation;
(ix) The quantity disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed; and
(x) The originals of all written certifications of available procurement quotas submitted by other persons (as required by §1303.12(f) of this chapter) relating to each order requiring the distribution of a basic class of controlled substance listed in Schedule I or II.

(2) For each controlled substance in finished form,

(i) The name of the substance;
(ii) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);
(iii) The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to paragraph (a)(1)(v) of this section;
(iv) The number of units of finished forms and/or commercial containers acquired from other persons, including the date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the person from whom the units were acquired;
(v) The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation;
(vi) The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

(A) The date and batch or other identifying number of each manufacture;
(B) The operation performed (e.g., repackaging or relabeling);
(C) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes for such losses, if known; and
(D) Such other information as is necessary to account for all controlled substances used in the manufacturing process;
(vii) The number of commercial containers distributed to other persons, including the date of and number of containers in each reduction from inventory, and the name, address, and registration number of the person to whom the containers were distributed;
(viii) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and
(ix) The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or
§ 1304.24 Records for distributors.

Each person registered or authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2)(i), (ii), (iv), (v), (vii), (viii) and (ix) of this section.

§ 1304.25 Records for dispensers and researchers.

Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person from whom the substance was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.

§ 1304.26 Records for importers and exporters.

Each person registered or authorized to import or export controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2)(i), (iv), (v) and (vii) of this section. In addition, the quantity disposed of in any other manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation, or destruction, and the name, address, and registration number, if any, of the person from whom the substance was received.

§ 1304.27 Records for chemical analysts.

(a) Each person registered or authorized (by §1301.22(b) of this chapter) to conduct chemical analysis with controlled substances shall maintain records with the following information (to the extent known and reasonably ascertainable by him) for each controlled substance:

(1) The name of the substance;

(2) The form or forms in which the substance is received, imported, or manufactured by the registrant (e.g., powder, granulation, tablet, capsule, or solution) and the concentration of the substance in such form (e.g., C.P., U.S.P., N.F., 10-milligram tablet or 10-milligram concentration per milliliter);

(3) The total number of the forms received, imported or manufactured (e.g., 100 tablets, thirty 1-milliliter vials, or 10 grams of powder), including the date and quantity of each receipt, importation, or manufacture and the name, address, and registration number, if any, of each person from whom the substance was received;

(4) The quantity distributed, exported, or destroyed in any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation, or destruction, and the name, address, and registration number, if any, of each person from whom the substance was distributed or exported.

(b) Records of controlled substances used in chemical analysis or other laboratory work are not required.

(c) Records relating to known or suspected controlled substances received as evidentiary material for analysis are not required under paragraph (a) of this section.

§ 1304.28 Records for maintenance treatment programs and detoxification treatment programs.

(a) Each person registered or authorized (by §1301.22 of this chapter) to maintain and/or detoxify controlled substances by destruction, including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.

(b) Records for dispensers. Each person registered or authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2)(i), (ii), (iv), (v), (vii), (viii) and (ix) of this section.

(c) Records for dispensers and researchers. Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.

(d) Records for importers and exporters. Each person registered or authorized to import or export controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2)(i), (iv), (v) and (vii) of this section. In addition, the quantity disposed of in any other manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation, or destruction, and the name, address, and registration number, if any, of the person from whom the substance was received;
§ 1304.25 Records for treatment programs which compound narcotics for treatment programs and other locations.

Each person registered or authorized by §1301.22 of this chapter to compound narcotic drugs for off-site use in a narcotic treatment program shall maintain records which include the following information for each narcotic drug:

(a) For each narcotic controlled substance in bulk form to be used in, or capable of use in, the compounding of the same or other non-controlled substances in finished form:
(1) The name of the substance;
(2) The quantity compounded in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch compounded;
(3) The quantity received from other persons, including the date and quantity of each receipt and the name, address and registration number of the other person from whom the substance was received;
(4) The quantity imported directly by the registrant (under a registration as an importer) for use in compounding by him, including the date, quantity and import permit or declaration number of each importation;
(5) The quantity used to compound the same substance in finished form, including:
   (i) The date and batch or other identifying number of each compounding;
   (ii) The quantity used in the compounding;
   (iii) The finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter;
   (iv) The number of units of finished form compounded;
   (v) The quantity used in quality control;
   (vi) The quantity lost during compounding and the causes therefore, if known;
   (vii) The total quantity of the substance contained in the finished form;
   (viii) The theoretical and actual yields; and
   (ix) Such other information as is necessary to account for all controlled substances used in the compounding process;
(b) The records required by paragraph (a) of this section will be maintained in a dispensing log at the narcotic treatment program site and will be maintained in compliance with §1304.22 without reference to §1304.03.
(c) All sites which compound a bulk narcotic solution from bulk narcotic powder to liquid for on-site use must keep a separate batch record of the compounding.
(d) Records of identity, diagnosis, prognosis, or treatment of any patients which are maintained in connection with the performance of a narcotic treatment program shall be confidential, except that such records may be disclosed for purposes and under the circumstances authorized by part 310 and 42 CFR part 2.

(b) For each narcotic controlled substance in finished form:
   (1) The name of the substance;
   (2) Each finished form (e.g., 10-milligram tablet or 10 milligram concentration per fluid ounce or milliliter) and the number of units or volume or finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);
   (3) The number of containers of each such commercial finished form compounded from bulk form by the registrant, including the information required pursuant to paragraph (a)(5) of this section;
   (4) The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address and registration number of the person from whom the units were received;
   (5) The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation;
   (6) The number of units and/or commercial containers compounded by the registrant from units in finished form received from others or imported, including:
      (i) The date and batch or other identifying number of each compounding;
      (ii) The operation performed (e.g., repackaging or relabeling);
      (iii) The number of units of finished form used in the compound, the number compounded and the number lost during compounding, with the causes for such losses, if known; and
      (iv) Such other information as is necessary to account for all controlled substances used in the compounding process;
   (7) The number of containers distributed to other programs, including the date, the number of containers in each distribution, and the name, address and registration number of the program to whom the containers were distributed;
   (8) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and
   (9) The number of units of finished forms and/or commercial containers destroyed in any manner by the registrant, including the reason, the date and manner of destruction. All other destruction of narcotic controlled substances will comply with §1307.22.


REPORTS

§ 1304.31 Reports from manufacturers importing narcotic raw material.

(a) Every manufacturer which imports or manufactures from narcotic raw material (opium, poppy straw, and concentrate of poppy straw) shall submit information which accounts for the importation and for all manufacturing operations performed between importation and the production in bulk or finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary or other recognized medical standards. Reports shall be signed by the authorized official and submitted quarterly on company letterhead to the Drug Enforcement Administration, Drug and Chemical Evaluation Section, Washington, D.C. 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The following information shall be submitted for each type of narcotic raw material (quantities are expressed as grams of anhydrous morphine alkaloid):
   (1) Beginning inventory;
   (2) Gains on reweighing;
   (3) Imports;
   (4) Other receipts;
   (5) Quantity put into process;
   (6) Losses on reweighing;
   (7) Other dispositions and
   (8) Ending inventory.

(c) The following information shall be submitted for each narcotic raw material derivative including morphine, codeine, thebaine, oxycodone, hydrocodone, medicinal opium, manufacturing opium, crude alkaloids and
§ 1304.32 Reports of manufacturers importing coca leaves.

(a) Every manufacturer importing or manufacturing from raw coca leaves shall submit information accounting for the importation and for all manufacturing operations performed between the importation and the manufacture of bulk or finished products standardized in accordance with U.S. Pharmacopoeia, National Formulary, or other recognized standards. The reports shall be submitted quarterly on company letterhead to the Drug Enforcement Administration, Drug and Chemical Evaluation Section, Washington, DC 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The following information shall be submitted for raw coca leaf, ecgonine, ecgonine for conversion or further manufacture, benzoylecgonine, manufacturing coca extracts (list for tinctures and extracts; and others separately), other crude alkaloids and other derivatives (quantities should be reported as grams of actual quantity involved and the cocaine alkaloid content or equivalency):

(1) Beginning inventory;
(2) Imports;
(3) Gains on reweighing;
(4) Quantity purchased;
(5) Quantity produced;
(6) Other receipts;
(7) Returns to processes for reworking;
(8) Material used in purification for sale;
(9) Material used for manufacture or production;
(10) Losses on reweighing;
(11) Material used for conversion;
(12) Other dispositions and
(13) Ending inventory.

(c) The following information shall be submitted for importation of coca leaves:

(1) Import permit number;
(2) Date the shipment arrived at the United States port of entry;
(3) Actual quantity shipped;
(4) Assay (percent) of morphine, codeine and thebaine and
(5) Quantity shipped, expressed as anhydrous morphine alkaloid.

(d) Upon importation of crude opium, samples will be selected and assays made by the importing manufacturer in the manner and according to the method specified in the U.S. Pharmacopoeia. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(e) Where factory procedure is such that partial withdrawals of opium are made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.

(f) All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it must no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.

§ 1304.33 Reports to ARCOS.

(a) Reports generally. All reports required by this section shall be filed with the ARCOS Unit, PO 28293, Central Station, Washington, DC 20005 on DEA Form 333, or on media which contains the data required by DEA Form 333 and which is acceptable to the ARCOS Unit.

(b) Frequency of reports. Acquisition/Distribution transaction reports shall be filed every quarter not later than the 15th day of the month succeeding the quarter for which it is submitted; except that a registrant may be given permission to file more frequently (but not more frequently than monthly), depending on the number of transactions being reported each time by that registrant.

(c) Persons reporting. For controlled substances in Schedules I, II or narcotic controlled substances in Schedule III, each person who is registered to manufacture in bulk or dosage form, or to package, repackage, label or relabel, and each person who is registered to distribute shall report acquisition/distribution transactions. In addition to reporting acquisition/distribution transactions, each person who is registered to manufacture controlled substances in bulk or dosage form shall report manufacturing transactions on controlled substances in Schedules I and II, each narcotic controlled substance listed in Schedules III, IV, and V, and on each psychotropic controlled substance listed in Schedules III and IV as identified in paragraph (d) of this section.

(d) Substances covered. (1) Manufacturing and acquisition/distribution transaction reports shall include data on each controlled substance listed in Schedules I and II and on each narcotic controlled substance listed in Schedule III (but not on any material, compound, mixture or preparation containing a quantity of a substance having a stimulant effect on the central nervous system, which material, compound, mixture or preparation is listed in Schedule III or on any narcotic controlled substance listed in Schedule V). Additionally, reports on manufacturing transactions shall include the following psychotropic controlled substances listed in Schedules III and IV:

   (i) Schedule III
      (A) Benzphetamine;
      (B) Cyclobarbital;
      (C) Methyprylon; and
      (D) Phendimetrazine.

   (ii) Schedule IV
      (A) Barbital;
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(B) Diethylpropion (Amfepramone);
(C) Ethchlorvynol;
(D) Ethinamate;
(E) Lefetamine (SPA);
(F) Mazindol;
(G) Meprobamate;
(H) Methylphenobarbital;
(I) Phenobarbital;
(J) Phentermine; and
(K) Pipradrol.

(2) Data shall be presented in such a manner as to identify the particular form, strength, and trade name, if any, of the product containing the controlled substance for which the report is being made. For this purpose, persons filing reports shall utilize the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration.

(e) Transactions reported. Acquisition/distribution transaction reports shall provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies). Manufacturing reports shall provide data on material manufactured, manufacture from other material, use in manufacturing other material and use in producing dosage forms.

(f) Exceptions. A registered institutional practitioner who repackages or relabels exclusively for distribution or who distributes exclusively to (for dispensing by) agents, employees, or affiliated institutional practitioners of the registrant may be exempted from filing reports under this section by applying to the ARCOS Unit of the Administration.

(Approved by the Office of Management and Budget under control number 1117–0003)


PART 1305—ORDER FORMS

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AUTHORITY: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.


§ 1305.01 Scope of part 1305.

Procedures governing the issuance, use, and preservation of order forms pursuant to section 1308 of the Act (21 U.S.C. 828) are set forth generally by that section and specifically by the sections of this part.

§ 1305.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.


§ 1305.03 Distributions requiring order forms.

An order form (DEA Form 222) is required for each distribution of a Schedule I or II controlled substance except to persons exempted from registration under part 1301 of this chapter; which are exported from the United States in conformity with the Act; or for delivery to a registered analytical laboratory, or its agent approved by DEA.


§ 1305.04 Persons entitled to obtain and execute order forms.

(a) Order forms may be obtained only by persons who are registered under section 303 of the Act (21 U.S.C. 823) to handle controlled substances listed in Schedules I and II, and by persons who are registered under section 1008 of the Act (21 U.S.C. 958) to export such substances. Persons not registered to handle controlled substances listed in
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Schedule I or II and persons registered only to import controlled substances listed in any schedule are not entitled to obtain order forms.

(b) An order form may be executed only on behalf of the registrant named thereon and only if his/her registration as to the substances being purchased has not expired or been revoked or suspended.


§ 1305.05 Procedure for obtaining order forms.

(a) Order Forms are issued in mailing envelopes containing either seven or fourteen forms, each form containing an original duplicate and triplicate copy (respectively, Copy 1, Copy 2, and Copy 3). A limit, which is based on the business activity of the registrant, will be imposed on the number of order forms which will be furnished on any requisition unless additional forms are specifically requested and a reasonable need for such additional forms is shown.

(b) Any person applying for a registration which would entitle him/her to obtain order forms may requisition such forms by so indicating on the application form; order forms will be supplied upon the registration of the applicant. Any person holding a registration entitling him/her to obtain order forms may requisition such forms for the first time by contacting any Division Office or the Registration Unit of the Administration. Any person already holding order forms may requisition additional forms on DEA Form 222a which is mailed to a registrant approximately 30 days after each shipment of order forms to that registrant or by contacting any Division Office or the Registration Unit of the Administration. All requisition forms (DEA Form 222a) shall be submitted to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005.

(c) Each requisition shall show the name, address, and registration number of the registrant and the number of books of order forms desired. Each requisition shall be signed and dated by the same person who signed the most recent application for registration or for reregistration, or by any person authorized to obtain and execute order forms by a power of attorney pursuant to §1305.07.

(d) Order forms will be serially numbered and issued with the name, address and registration number of the registrant, the authorized activity and schedules of the registrant. This information cannot be altered or changed by the registrant; any errors must be corrected by the Registration Unit of the Administration by returning the forms with notification of the error.


§ 1305.06 Procedure for executing order forms.

(a) Order forms shall be prepared and executed by the purchaser simultaneously in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms shall be prepared by use of a typewriter, pen, or indelible pencil.

(b) Only one item shall be entered on each numbered line. An item shall consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The number of lines completed shall be noted on that form at the bottom of the form, in the space provided. Order forms for carfentanil, etorphine hydrochloride, and diprenorphine shall contain only these substances.

(c) The name and address of the supplier from whom the controlled substances are being ordered shall be entered on the form. Only one supplier may be listed on any form.

(d) Each order form shall be signed and dated by a person authorized to sign an application for registration. The name of the purchaser, if different from the individual signing the order form, shall also be inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location.
§ 1305.07 Power of attorney.

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a power of attorney for each such individual. The power of attorney shall be signed by the same person who signed the most recent application for registration or reregistration and by the individual being authorized to obtain and execute order forms. The power of attorney shall be filed with the executed order forms of the purchaser, and shall be retained for the same period as any order form bearing the signature of the attorney. The power of attorney shall be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a notice of revocation, signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, whoever signed the most recent application for registration or reregistration, and filing it with the power of attorney being revoked. The form for the power of attorney and notice of revocation shall be similar to the following:

Power of Attorney for DEA Order Forms

(Name of registrant)

(Address of registrant)

(DEA registration number)

I, _______________ (name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint _______________ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for Schedule I and II controlled substances, in accordance with section 308 of the Controlled Substances Act (21 U.S.C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

(Signature of person granting power)

I, _______________ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

(Signature of attorney-in-fact)

Witnesses:
1. _______________,
2. _______________.
Signed and dated on the __________ day of ______________, (year), at ______________.

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact ______________ this same day.

(Signature of person revoking power)

Witnesses:
1. _______________,
2. _______________.
Signed and dated on the __________ day of ______________, (year), at ______________.

§ 1305.08 Persons entitled to fill order forms.

An order form may be filled only by a person registered as a manufacturer or distributor of controlled substances listed in Schedule I or II under section 303 of the Act (21 U.S.C. 823) or as an importer of such substances under section 1008 of the Act (21 U.S.C. 958), except for the following:

(a) A person registered to dispense such substances under section 303 of the Act, or to export such substances under section 1008 of the Act, if he/she is discontinuing business or if his/her registration is expiring without reregistration, may dispose of any controlled substances in Schedule I or II in his/her possession pursuant to order forms in accordance with §1307.14 of this chapter;

(b) A person who has obtained any controlled substance in Schedule I or II
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by order form may return such sub-
stance, or portion thereof, to the per-
son from whom he obtained the sub-
stance or the manufacturer of the sub-
stance pursuant to the order form of
the latter person;
(c) A person registered to dispense
such substances may distribute such
substances to another dispenser pursu-
ant to, and only in the circumstances
described in, §1307.11 of this chapter;
and
(d) A person registered or authorized
to conduct chemical analysis or re-
search with controlled substances may
distribute a controlled substance listed
in Schedule I or II to another person
registered or authorized to conduct
chemical analysis, instructional activi-
ties, or research, with such substances
pursuant to the order form of the lat-
ter person, if such distribution is for
the purpose of furthering such chem-
ical analysis, instructional activities,
or research.

§ 1305.09 Procedure for filling order
forms.

(a) The purchaser shall submit Copy 1
and Copy 2 of the order form to the
supplier, and retain Copy 3 in his own
files.
(b) The supplier shall fill the order, if
possible and if he/she desires to do so,
and record on Copies 1 and 2 the num-
er of commercial or bulk containers
furnished on each item and the date on
which such containers are shipped to
the purchaser. If an order cannot be
filled in its entirety, it may be filled in
part and the balance supplied by addi-
tional shipments within 60 days fol-
lowing the date of the order form. No
order form shall be valid more than 60
days after its execution by the pur-
chaser, except as specified in paragraph
(f) of this section.
(c) The controlled substances shall
only be shipped to the purchaser and at
the location printed by the Adminis-
tration on the order form, except as
specified in paragraph (f) of this sec-
tion.
(d) The supplier shall retain Copy 1 of
the order form for his/her own files and
forward Copy 2 to the Special Agent in
Charge of the Drug Enforcement Ad-
ministration in the area in which the
supplier is located. Copy 2 shall be for-
warded at the close of the month dur-
ing which the order is filled; if an order
is filled by partial shipments, Copy 2
shall be forwarded at the close of the
month during which the final shipment
is made or during which the 60-day va-

d validity period expires.
(e) The purchaser shall record on
Copy 3 of the order form the number of
commercial or bulk containers fur-
nished on each item and the dates on
which such containers are received by
the purchaser.
(f) Order forms submitted by reg-
istered procurement officers of the De-
fense Personnel Support Center of De-
fense Supply Agency for delivery to
armed services establishments within
the United States may be shipped to lo-
cations other than the location printed
on the order form, and in partial ship-
ments at different times not to exceed
six months from the date of the order,
as designated by the procurement offi-
cer when submitting the order.

§ 1305.10 Procedure for endorsing
order forms.

(a) An order form made out to any
supplier who cannot fill all or a part of
the order within the time limitation
set forth in §1305.09 may be endorsed
to another supplier for filling. The en-
dorsement shall be made only by the
supplier to whom the order form was
§ 1305.11 Unaccepted and defective order forms.

(a) No order form shall be filled if it:
(1) Is not complete, legible, or properly prepared, executed, or endorsed; or
(2) Shows any alteration, erasure, or change of any description.

(b) If an order form cannot be filled for any reason under this section, the supplier shall return Copies 1 and 2 to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted shall be sufficient for purposes of this paragraph.

(c) When received by the purchaser, Copies 1 and 2 of the order form and the statement shall be attached to Copy 3 and retained in the files of the purchaser in accordance with §1305.13. A defective order form may not be corrected; it must be replaced by a new order form in order for the order to be filled.

§ 1305.12 Lost and stolen order forms.

(a) If a purchaser ascertains that an unfilled order form has been lost, he/she shall execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods covered by the first order form were not received through loss of that order form. Copy 3 of the second form and a copy of the statement shall be retained with Copy 3 of the order form first executed. A copy of the statement shall be attached to Copies 1 and 2 of the second order form sent to the supplier. If the first order form is subsequently received by the supplier to whom it was directed, the supplier shall mark upon the face thereof “Not accepted” and return Copies 1 and 2 to the purchaser, who shall attach it to Copy 3 and the statement.

(b) Whenever any used or unused order forms are stolen or lost (otherwise than in the course of transmission) by any purchaser or supplier, he/she shall immediately upon discovery of such theft or loss, report the same to the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located, stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, he/she shall report the date or approximate date of receipt thereof and the names and addresses of the purchasers. If an entire book of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms contained therein, he/she shall report, in lieu of the numbers of the forms contained in such book, the date or approximate date of issuance thereof. If any unused order form reported stolen or lost is subsequently recovered or found, the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located shall immediately be notified.

§ 1305.13 Preservation of order forms.

(a) The purchaser shall retain Copy 3 of each order form which has been filled. He/She shall also retain in his...
files all copies of each unaccepted or defective order form and each statement attached thereto.

(b) The supplier shall retain Copy 1 of each order form which he/she has filled.

(c) Order forms must be maintained separately from all other records of the registrant. Order forms are required to be kept available for inspection for a period of 2 years. If a purchaser has several registered locations, he/she must retain Copy 3 of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to §1305.06(d)) at the registered location printed on the order form.

(d) The supplier of carfentanil etorphine hydrochloride and diprenorphine shall maintain order forms for these substances separately from all other order forms and records required to be maintained by the registrant.

§1305.14 Return of unused order forms.

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on his registration) or is suspended or revoked pursuant to §1301.30 of this chapter as to all controlled substances listed in Schedules I and II for which he/she is registered, he/she shall return all unused order forms for such substance to the nearest office of the Administrator.

§1305.15 Cancellation and voiding of order forms.

(a) A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier shall indicate the cancellation on Copies 1 and 2 of the order form by drawing a line through the canceled items and printing "canceled" in the space provided for number of items shipped.

(b) A supplier may void part or all of an order on an order form by notifying the purchaser in writing of such voiding. The supplier shall indicate the voiding in the manner prescribed for cancellation in paragraph (a) of this section.

(c) No cancellation or voiding permitted by this section shall affect in any way contract rights of either the purchaser or the supplier.

§1305.16 Special procedure for filling certain order forms.

(a) The purchaser of carfentanil etorphine hydrochloride or diprenorphine shall submit copy 1 and 2 of the order form to the supplier and retain copy 3 in his own files.

(b) The supplier, if he/she determines that the purchaser is a veterinarian engaged in zoo and exotic animal practice, wildlife management programs and/or research and authorized by the Administrator to handle these substances shall fill the order in accordance with the procedures set forth in §1305.09 except that:

(1) Order forms for carfentanil etorphine hydrochloride and diprenorphine shall only contain these substances in reasonable quantities and

(2) The substances shall only be shipped to the purchaser at the location printed by the Administration upon the order form under secure conditions using substantial packaging material with no markings on the outside which would indicate the content.
§ 1306.01 Scope of part 1306.

Rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829) are set forth generally in that section and specifically by the sections of this part.

§ 1306.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

(62 FR 13964, Mar. 24, 1997)

§ 1306.03 Persons entitled to issue prescriptions.

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

(1) authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and

(2) either registered or exempted from registration pursuant to §§ 1301.22(c) and 1301.23 of this chapter.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.


§ 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for “detoxification treatment” or “maintenance treatment” as defined in Section 102 of the Act (21 U.S.C. 802).


§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address, and date of issue.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

and registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these regulations.

(b) An individual practitioner exempted from registration under §1301.22(c) of this chapter shall include on all prescriptions issued by him or her the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in §1301.22(c) of this chapter, in lieu of the registration number of the practitioner required by this section. Each written prescription shall have the name of the physician stamped, typed, or handprinted on it, as well as the signature of the physician.

(c) An official exempted from registration under §1301.22(c) shall include on all prescriptions issued by him his branch of service or agency (e.g., “U.S. Army” or “Public Health Service”) and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.

§ 1306.11 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (d) of this section. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner’s agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section. The original prescription shall be maintained in accordance with §1304.04(h) of this chapter.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to §1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, as defined by the Secretary in §290.10 of this title, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner; provided that:

1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);

2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in §1306.05, except for the signature of the prescribing individual practitioner;

3. If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and

4. Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of §1306.05, the prescription shall have written on its face “Authorization for Emergency Dispensing,” and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

(e) A prescription prepared in accordance with §1306.05 written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner’s agent to the pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (e) and it shall be maintained in accordance with §1304.04(h) of this chapter.
(f) A prescription prepared in accordance with §1306.05 written for Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner’s agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (f) and it shall be maintained in accordance with §1304.04(h).

(g) A prescription prepared in accordance with §1306.05 written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner’s agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner’s agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with §1304.04(h).

§ 1306.13 Partial filling of prescriptions.

(a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is “terminally ill” or an “LTCF patient.” A prescription that is partially filled and does not contain the notation “terminally ill” or “LTCF patient” shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

(c) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:

(1) Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address
§ 1306.14 Labeling of substances and filling of prescriptions.

(a) The pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

(b) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized: Provided, That:

1. Not more than 7-day supply of the controlled substance listed in Schedule II is dispensed at one time;
2. The controlled substance listed in Schedule II is not in the possession of the ultimate user prior to the administration;
3. The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule II; and
4. The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

(c) All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of §1304.04(h) of this chapter.

§ 1306.21 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner’s agent to the pharmacy or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in §1306.05, except for the signature of the practitioner.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule III, IV, or V in the course of his/her professional practice without a prescription, subject to §1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III, IV, or V only pursuant to a written prescription signed by an individual practitioner, or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in Section 1306.05 except for the signature of the individual practitioner, or pursuant to an order for medication made by an individual pharmacist.
§ 1306.22 Refilling of prescriptions.

(a) No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times. Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document. If entered on another document, such as a medication record, the document must be uniformly maintained and readily retrievable. The following information must be retrievable by the prescription number consisting of the name and dosage form of the controlled substance, the date filled or refilled, the quantity dispensed, initials of the dispensing pharmacist for each refill, and the total number of refills for that prescription. If the pharmacist merely initials and dates the back of the prescription it shall be deemed that the full face amount of the prescription has been dispensed. The prescribing practitioner may authorize additional refills of Schedule III or IV controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

(1) The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issue of the original prescription.

(2) The pharmacist obtaining the oral authorization records on the reverse of the original prescription the date, quantity of refill, number of additional refills authorized, and initials the prescription showing who received the authorization from the prescribing practitioner who issued the original prescription.

(3) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

(4) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five refill, six-month limitation.

(b) As an alternative to the procedures provided by subsection (a), an automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

(1) Any such proposed computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address, and DEA registration number of the practitioner, and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

(2) Any such proposed computerized system must also provide on-line retrieval (via CRT display or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months.) This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. If such a system provides a hard-copy printout of each day’s controlled substance prescription order refill data, that printout shall be
verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J. H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day’s controlled substance prescription order refill data must be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

(4) Any such computerized system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining under the Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must include name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized system employed by a user pharmacy the central record-keeping location must be capable of sending the printout to the pharmacy within 48 hours, and if a DEA Special Agent or Diversion Investigator requests a copy of such printout from the user pharmacy, it must, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its system by documentation (e.g., postmark).

(5) In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills on Schedule III and IV controlled substance prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

(c) When filing refill information for original prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two systems described in paragraphs (a) or (b) of this section.

(a) The transfer of original prescription information for a controlled substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber’s authorization. Transfers are subject to the following requirements:

(i) Write the word “VOID” on the face of the invalidated prescription.
(ii) Record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist transferring the prescription.
(iii) Record the date of the transfer and the name of the pharmacist transferring the information.

(b) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(i) Write the word “transfer” on the face of the transferred prescription.

(2) Provide all information required to be on a prescription pursuant to 21 CFR 1306.05 and include:

(i) Date of issuance of original prescription;
(ii) Original number of refills authorized on original prescription;
(iii) Date of original dispensing;
(iv) Number of valid refills remaining and date(s) and locations of previous refill(s);
(v) Pharmacy’s name, address, DEA registration number and prescription number from which the prescription information was transferred;
(vi) Name of pharmacist who transferred the prescription.
(vii) Pharmacy’s name, address, DEA registration number and prescription number from which the prescription was originally filled;

(3) The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.

(c) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferral.

(d) The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing state or other applicable law.

§ 1306.26 Dispensing without prescription.

A controlled substance listed in Schedules II, III, IV, or V which is not a prescription drug as determined...
under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(a) Such dispensing is made only by a pharmacist (as defined in part 1300 of this chapter), and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);

(b) Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;

(c) The purchaser is at least 18 years of age;

(d) The pharmacist requires every purchaser of a controlled substance under this section not known to him to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of §1304.04 of this chapter); and

(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law.

§ 1307.03 Exceptions to regulations.

Any person may apply for an exception to the application of any provision of this chapter by filing a written request stating the reasons for such exception. Requests shall be filed with the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537. The Administrator may grant an exception in his discretion, but in no case shall he/she be required to grant an exception to any person which is otherwise required by law or the regulations cited in this section.


§ 1307.11 Distribution by dispenser to another practitioner.

(a) A practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to another practitioner for the purpose of general dispensing by the practitioner to his or its patients: Provided, That:

(1) The practitioner to whom the controlled substance is to be distributed is registered under the Act to dispense that controlled substance;

(2) The distribution is recorded by the distributing practitioner in accordance with §1304.22(c) of this chapter and by the receiving practitioner in accordance with §1304.22(c) of this chapter;

(3) If the substance is listed in Schedule I or II, an order form is used as required by part 1305 of this chapter;

(4) The total number of dosage units of all controlled substances which will be distributed by him pursuant to this section and §1301.25 of this chapter will exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by him during that calendar year, the practitioner shall obtain a registration to distribute controlled substances.


§ 1307.12 Distribution to supplier.

(a) Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he obtained it or to the manufacturer of the substance, provided that a written record is maintained which indicates the date of the transaction, the name, form, and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and the name, address, and registration number, if known, of the supplier or manufacturer. In the case of returning a controlled substance in Schedule I or II, an order form shall be used in the manner prescribed in part 1305 of this chapter and be maintained as the written record of the transaction. Any person not required to register pursuant to sections 302(c) or 1007(b)(1) of the Act (21 U.S.C. 822(c) or 957(b)(1)) shall be exempt from maintaining the records required by this section.

(b) Distributions referred to in paragraph (a) may be made through a freight forwarding facility operated by the person to whom the controlled substance is being returned provided that prior arrangement has been made for the return and the person making the distribution delivers the controlled substance directly to an agent or employee of the person to whom the controlled substance is being returned.

[65 FR 44679, July 19, 2000; 65 FR 45829, July 25, 2000]
§ 1307.13 Incidental manufacture of controlled substances.

Any registered manufacturer who, incidentally but necessarily, manufactures a controlled substance as a result of the manufacture of a controlled substance or basic class of controlled substance for which he is registered and has been issued an individual manufacturing quota pursuant to part 1303 of this chapter (if such substance or class is listed in Schedule I or II) shall be exempt from the requirement of registration pursuant to part 1301 of this chapter and, if such incidentally manufactured substance is listed in Schedule I or II, shall be exempt from the requirement of an individual manufacturing quota pursuant to part 1303 of this chapter, if such substances are disposed of in accordance with § 1307.21.

§ 1307.21 Procedure for disposing of controlled substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant, he/she shall list the controlled substance or substances which he/she desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his/her area; or

(2) If the person is not a registrant, he/she shall submit to the Special Agent in Charge a letter stating:

(i) The name and address of the person;

(ii) The name and quantity of each controlled substance to be disposed of;

(iii) How the applicant obtained the substance, if known; and

(iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

(b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By delivery to an agent of the Administration or to the nearest office of the Administration;

(3) By destruction in the presence of an agent of the Administration or other authorized person; or

(4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

(c) In the event that a registrant is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the registrant to dispose of such substances, in accordance with paragraph (b) of this section, without prior approval of the Administration in each instance, on the condition that the registrant keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals made by the registrant. In granting such authority, the Special Agent in Charge may place such conditions as he deems proper on the disposal of controlled substances, including the method of disposal and the frequency and detail of reports.

(d) This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any State.

§ 1307.22 Disposal of controlled substances by the Administration.

Any controlled substance delivered to the Administration under § 1307.21 or forfeited pursuant to section 511 of the Act (21 U.S.C. 881) may be delivered to any department, bureau, or other agency of the United States or of any State upon proper application addressed to the Administrator, Drug Enforcement...
Drug Enforcement Administration, Justice

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Administration, Department of Justice, Washington, DC 20537 The application shall show the name, address, and official title of the person or agency to whom the controlled drugs are to be delivered, including the name and quantity of the substances desired and the purpose for which intended. The delivery of such controlled drugs shall be ordered by the Administrator, if, in his opinion, there exists a medical or scientific need therefor.


SPECIAL EXEMPT PERSONS

§ 1307.31 Native American Church. The listing of peyote as a controlled substance in Schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the Native American Church so using peyote are exempt from registration. Any person who manufactures peyote for or distributes peyote to the Native American Church, however, is required to obtain registration annually and to comply with all other requirements of law.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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AUTHORITY: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.


GENERAL INFORMATION

§ 1308.01 Scope of part 1308.

Schedules of controlled substances established by section 202 of the Act (21 U.S.C. 812), as they are changed, updated, and republished from time to time, are set forth in this part.

§ 1308.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.


§ 1308.03 Administration Controlled Substances Code Number.

(a) Each controlled substance, or basic class thereof, has been assigned an “Administration Controlled Substances Code Number” for purposes of identification of the substances or class on certain Certificates of Registration issued by the Administration pursuant to §§1301.35 of this chapter.

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§ 1308.11 and on certain order forms issued by the Administration pursuant to §1305.05(d) of this chapter. Applicants for procurement and/or individual manufacturing quotas must include the appropriate code number on the application as required in §§1303.12(b) and 1303.22(a) of this chapter. Applicants for import and export permits must include the appropriate code number on the application as required in §§1312.12(a) and 1312.22(a) of this chapter.

(b) Except as stated in paragraph (a) of this section, no applicant or registrant is required to use the Administration Controlled Substances Code Number for any purpose.

§ 1308.11 Schedule I.

(a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers and salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation (for purposes of paragraph (b)(3) only, the term isomer includes the optical and geometric isomers):

1. Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide) 9815
2. Acetylmethadol 9601
3. Alylprodine 9602
4. Alpha-hexamethadol (except levo-alpha-hexamethadol also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM) 9603
5. Alphaxanodione 9625
6. Alphamethadol 9605
7. Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl(ethyl-4-piperidyl) propionanilide]-1-(1-methyl-2-phenylethyl)-4-(N-propanoicid) piperidine) 9814
8. Alpha-methylofenidylfentanyl (N-[1-(methyl-2-(2-thienyl)ethyl-4-piperidinyl)]-N-phenylpropanamide) 9832
9. Benzethidine 9606
10. Betacetylmethadol 9607
11. Beta-hydroxyfenidylfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide) 9830
12. Beta-hydroxy-3-methylfenidylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide) 9831
13. Betamethadol 9609
14. Betaprodine 9608
15. Beta-properidine 9607
16. Betadizafadine 9611
17. Betamorephine 9612
18. Dextrorormorphan 9613
19. Dextromoramide 9615
20. Difentoxin 9168
21. Dimeoxadol 9617
22. Dimephenetol 9618
23. Dimethyllambutene 9619
24. Dioxaphetyl butyrate 9621
25. Dipipadine 9622
26. Ethylmethylimbutene 9623
27. Ethalamidine 9624
28. Exorzone 9625
29. Furethidine 9626
30. Hydroxyprolanide 9627
31. Ketorome 9628
32. Levomoramide 9629
33. Levophenacylomorphin 9631
34. 3-Methylfentanyl (N-[3-methyl-1-(2-phenethyl)-4-piperidinyl]-N-phenylpropanamide) 9813
35. 3-methyltetrahydronifenidylfentanyl (N-[3-methyl-1-(2-phenethyl)-4-piperidinyl]-N-phenylpropanamide) 9833
36. Mephenidine 9632
37. MPP (1-methyl-4-phenyl-4-propionoxypiperidine) 9661
38. Noracymethadol 9633
39. Norfopranol 9634
40. Normethadone 9635
41. Norpropadine 9636
42. Para-flurofenidyl (N-[4-fluorophenyl]-N-[1-(2-phenethyl)-4-piperidinyl] propanamide) 9812
43. PEPAP (1-[1-(2-phényl-4-phenyl-4-acetoxypiperidinyl]-N-phenylpropanamide) 9663
44. Phenadoxone 9637
45. Phenepridone 9638
46. Phenomorphan 9647
47. Pheneperidine 9641
48. Pheneraceine 9642
49. Phenoethidine 9643
50. Propinadine 9644
51. Propiram 9649
52. Racemoramide 9645
53. Thiofenadol (N-[phenyl-N]-[1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide) 9835
54. Tildine 9750
55. Trimeperidine 9646

(c) Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
(d) Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this paragraph only, the term “isomer” includes the optical, position and geometric isomers):

(1) Alpha-ethyltryptamine .......................................................... 7249
   Some trade or other names: etryptamine; Monase; α-ethyl-1H-indole-3-ethanamine; 3-(2-aminoisobutyryloxy)indole; α-ET; and AET.  
(2) 4-bromo-2,5-dimethoxyamphetamine .................. 7391
   Some trade or other names: 4-bromo-2,5-dimethoxy-α-methylphenylethylamine; 4-bromo-2,5-DMA.  
(3) 4-bromo-2,5-dimethoxyphenylethylamine .................. 7392
   Some trade or other names: 2-(4-bromo-2,5-dimethoxyphenyl)-1-aminoethane; α-desmethyl DOE; 2C-B, Nexus.  
(4) 2,5-dimethoxyamphetamine .............................................. 7396
   Some trade or other names: 2,5-dimethoxy-α-methylphenylethylamine; 2,5-DMA.  
(5) 2,5-dimethoxy-4-ethylamphetamine ...................... 7399
   Some trade or other names: DOET.  
(6) 4-methoxyamphetamine .................................................. 7411
   Some trade or other names: 4-methoxy-α-methylphenylethylamine; paramethoxyamphetamine, PMA.  
(7) 5-methoxy-3,4-methylenedioxyamphetamine .................. 7401
(8) 4-methyl-2,5-dimethoxyamphetamine .................. 7395
   Some trade or other names: 4-methyl-2,5-dimethoxy-α-methylphenylethylamine; "DOM"; and "STP".  
(9) 3,4-methylenedioxyamphetamine .................. 7400
(10) 3,4-methylenedioxymethamphetamine (MDMA) .... 7405
(11) 3,4-methylenedioxyn-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4-methylenedioxyphenylethylamine, N-ethyl MDA, MDEA, MDE) 7404
(12) N-hydroxy-3,4-methylenedioxyamphetamine (also known as N-hydroxy-alpha-methyl-3,4-methylenedioxyphenylethylamine, and N-hydroxy MDA) 7402
(13) 3,4,5-trimethoxyamphetamine .................. 7390
(14) Butyroline ...................................................... 7433
   Some trade or other names: 3-[(1-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-Dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethylyryptamine; mappine.  
(15) Dietytryptamine .............................................. 7343
   Some trade or other names: N,N-Dietytryptamine; DET.  
(16) Dihydrotryptamine .............................................. 7345
   Some trade or other names: DMT.  
(17) Ilogaine .......................................................... 7260
   Some trade or other names: 7-Ethyl-6,6,7,8,9,10,12,13-octahydro-2-methoxy-6,9-dimethano-5H-pyrido [1, 2:1,2] azepino [5,4-b] indole; Tabernanthe iboga.  
(18) Lysergic acid diethylamide ...................................... 7315
(19) Mariguana.......................................................... 7360
(20) Mescaline .......................................................... 7381
(21) Parahexyl—7374; some trade or other names: 3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-benzoo[3,4-b]pyran; Synhexyl.  
(22) Peyote .......................................................... 7415
   Meaning all parts of the plant presently classified botanically as Lophophora Williamsii Lemaire, whether growing or not, the seeds thereof, any part from any of such plant, and every compound, mixture, or preparation of such plant, its seeds or extracts (interprets 21 USC 812(c), Schedule I(c) (12)).  
(23) N-ethyl-3-piperidyl benzilate .................. 7482
(24) N-methyl-3-piperidyl benzilate .................. 7484
(25) Psilocybin ........................................................... 7437
(26) Psilocyn .......................................................... 7438
(27) Tetrahydrocannabinols .............................................. 7370
   Synthetic equivalents of the substances contained in the plant, or in the resinous extracts of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:
   3α cis or trans tetrahydrocannabinol, and their optical isomers.  
   3α cis or trans tetrahydrocannabinol, and their optical isomers.  
   3α,4 cis or trans tetrahydrocannabinol, and its optical isomers.
   (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)  
(28) Ethylamine analog of phenocyclidine .................. 7455
   Some trade or other names: N-ethyl-1-phenylcyclohexylamine, 1-phenylcyclohexylethylamine, N-[1-phenylcyclohexyl]ethylamine, cyclohexamine, PCE.  
(29) Pyrrolidine analog of phenocyclidine .................. 7458
   Some trade or other names: 1-[1-phenylcyclohexyl]-pyrrolidine, PGPY, PHP.  
(30) Thiophene analog of phenocyclidine .................. 7470
   Some trade or other names: 1-[1-(2-thienyl)cyclohexyl]piperidine, 2-thienyl analog of phenocyclidine, TPCC, TCP.  
(31) 1-[1-(2-thienyl)cyclohexyl]pyrrolidine .................. 7473
   Some other names: TCPy.  

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains...
any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) gamma-hydroxybutyric acid (some other names include GHB; gamma-hydroxybutyrate; 4-hydroxybutyric acid; sodium oxybate; sodium oxybutyrate) .............................................. 2010
(2) Mechoqualone ............................................................. 2572
(3) Methaqualone .............................................................. 2565

(f) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Aminorex (Some other names: aminophenyl, 2-amino-5-phenyl-2-oxazoline; or 4,5-dihydro-5-phenyl-2-oxazolamine) ................................................................. 1565
(2) Cathinone ................................................................ 1235

Some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrine

(3) Fenethylline ............................................................... 1503
(4) Methcathinone (Some other names: 2-(methylamino)-propiophenone; alpha-(methylamino)propiophenone; 2-(methylamino)-1-phenylprop-1-one; alpha-N-methylaminoisopropiophenone; monomethylpropion; epiphenedrone; N-methylicathinone; methylcathinone; AL-464; AL-462; AL-463 and UR1432), its salts, optical isomers and salts of optical isomers ........................................ 1237
(5) (1S,4R)-4-methylaminorex ((1S,4R)-cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine) ................................................................. 1590
(6) N-ethylamphetamine ..................................................... 1475
(7) N,N-dimethylamphetamine (also known as N,N-alpha-trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine) .................................................. 1480

(g) Temporary listing of substances subject to emergency scheduling. Any material, compound, mixture or preparation which contains any quantity of the following substances:

(1) N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (bentylfentanyl), its optical isomers, salts and salts of isomers .......................................................... 9818
(2) N-[2-(thienyl)ethyl]-4-piperidyl]-N-phenylpropanamide (thienylfenitamine), its optical isomers, salts and salts of isomers ................................................. 9834

39 FR 22141, June 20, 1974

EDITORIAL NOTE: For Federal Register citations affecting §1308.11, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 1308.12 Schedule II.

(a) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.

(b) Substances, vegetable origin or chemical synthesis. Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrophan, nalbuphine, nalbufine, naltroxone, and their respective salts, but including the following:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Code Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw opium</td>
<td>9600</td>
</tr>
<tr>
<td>Opium extracts</td>
<td>9610</td>
</tr>
<tr>
<td>Opium fluid</td>
<td>9620</td>
</tr>
<tr>
<td>Powdered opium</td>
<td>9639</td>
</tr>
<tr>
<td>Granulated opium</td>
<td>9640</td>
</tr>
<tr>
<td>Tincture of opium</td>
<td>9630</td>
</tr>
<tr>
<td>Codeine</td>
<td>9050</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>9334</td>
</tr>
<tr>
<td>Ethylmorphine</td>
<td>9190</td>
</tr>
<tr>
<td>Etorphine hydrochloride</td>
<td>9059</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>9193</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>9150</td>
</tr>
<tr>
<td>Metopon</td>
<td>9060</td>
</tr>
<tr>
<td>Morphine</td>
<td>9300</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>9143</td>
</tr>
<tr>
<td>Oxymorphine</td>
<td>9652</td>
</tr>
<tr>
<td>Thebaine</td>
<td>9333</td>
</tr>
</tbody>
</table>

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (b) (1) of this section, except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves (9040) and any salt, compound, derivative or preparation of coca leaves (including cocaine (9041) and ecgonine (9180) and their salts, isomers, derivatives and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances...
shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrene alkaloids of the opium poppy), 9670.

(c) Opiates. Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

(1) Alphaprodine ................................................................. 9010
(2) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; P2P; benzyl methyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(3) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(4) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(5) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(6) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(7) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(8) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(9) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(10) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(11) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(12) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(13) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(14) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(15) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(16) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(17) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(18) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(19) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(20) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(21) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(22) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(23) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(24) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(25) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(26) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254
(27) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Alphaprodine; some other names: phenyl-2-propanone; benzyl methyl ketone; methyl benzyl ketone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254

(f) Hallucinogenic substances.

(1) Nabilone ................................................................. 7379
[Another name for nabilone: (±)-trans-3-(1,1-dimethylethyl)-6,6a,7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzo[b,d]pyran-9-one]

(g) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

(i) Phenylacetone ................................. 8501
Some trade or other names: phenyl-2-propanone; (1R,3S,8S)-trans-2-dimethylamino-4,4-diphenyl butane .......................... 9254

(2) Immediate precursors to phencyclidine (PCP):

(i) 1-phenylcyclohexylamine ....................... 7460
(ii) 1-piperidinocyclohexanecarbonitrile (PCC) .. 8603

[39 FR 22142, June 20, 1974]

EDITORIAL NOTE: For Federal Register citations affecting §1308.12, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.
the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under §1308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances

(2) Benzphetamine ...................................................... 2928
(3) Chlorphenmetrazine .............................................. 2271
(4) Clioctrine .............................................................. 1647
(5) Phendimetrazine .................................................... 1615

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture or preparation containing:
   (i) Amobarbital ...................................................... 2126
   (ii) Secobarbital ..................................................... 2316
   (iii) Pentobarbital .................................................. 2271
   or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.

(2) Any suppository dosage form containing:
   (i) Amobarbital ...................................................... 2126
   (ii) Secobarbital ..................................................... 2316
   (iii) Pentobarbital .................................................. 2271
   or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.

(3) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof ....... 2100
(4) Chlorhexadol ........................................................ 2510
(5) Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act ................................................... 2012
(6) Ketamine, its salts, isomers, and salts of isomers .. 7285
   [Some other names for ketamine: (5S)-(2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone]
(7) Lysergic acid ......................................................... 7300
(8) Lysergic acid amide ............................................... 7310
(9) Methyprylon ......................................................... 1228
(10) Sulfonmethane ..................................................... 2610
(11) Sulfonethylmethane ................................................ 2605
(12) Sulfonmethylmethane ............................................. 1615
(13) Talazol and zolazepam or any salt thereof ......... 7295
   Some trade or other names for a talazol-zolazepam combination product:
   TelaZol.
   Some trade or other names for talazoline:
   2-(ethylamino)-2-(2-thienyl)cyclohexanone.
   Some trade or other names for zolazepam:
   4-(2-fluorophenyl)-6,8-dihyro-1,3,8-trimethylypyrazolo [3,4-e] [1,4]diazepin-7(1H)-one, flupyrAzapine.

(d) Nalorphine 9400.

(e) Narcotic Drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium .......... 9803
(2) Not more than 3.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts .................. 9804
(3) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium .... 9805
(4) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts .................. 9806
(5) Not more than 1.8 grams of dihydrocodeinone per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts .................. 9807
(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts .................. 9808
(7) Not more than 500 milligrams of opium per 100 milliliters or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts .................. 9809
(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts .................. 9810

(f) Anabolic steroids. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts of isomers is possible within the specific chemical designation:

(1) Anabolic Steroids ................................................. 4000

(g) Hallucinogenic substances.

(1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product—7389.

   [Some other names for dronabinol: (6aR,trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-penty1-6H-dibenzo [b,d]pyran-1-ol] or (−)-delta-9-(trans)-tetrahydrocannabinol]
§ 1308.14 Schedule IV.

(a) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible:

(1) Not more than 1 milligram of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit ___________________________ 9167
(2) Dextropropoxyphene (alpha-+4-(dimethylamino)-1,2-diphenyl-3-methyl-2-propoxybutane) ___________________________ 9278

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Alprazolam ___________________________ 2882
(2) Barbital ___________________________ 2145
(3) Bromazepam ___________________________ 2748
(4) Camazepam ___________________________ 2749
(5) Chloral betaine ___________________________ 2460
(6) Chloral hydrate ___________________________ 2465
(7) Chlordiazepoxide ___________________________ 2744
(8) Ciobazam ___________________________ 2751
(9) Cloazepam ___________________________ 2737
(10) Clonazepate ___________________________ 2768
(11) Clotiazepam ___________________________ 2752
(12) Cloxazolam ___________________________ 2753
(13) Delorazepam ___________________________ 2754
(14) Diazepam ___________________________ 2765
(15) Estazolam ___________________________ 2756
(16) Ethchlorvynol ___________________________ 2540
(17) Ethinamate ___________________________ 2545
(18) Ethyl lofzaepate ___________________________ 2758
(19) Fludiazepam ___________________________ 2759
(20) Flunitrazepam ___________________________ 2763
(21) Flurazepam ___________________________ 2767
(22) Halazepam ___________________________ 2762
(23) Haloxazolam ___________________________ 2771
(24) Ketazolam ___________________________ 2772
(25) Lorazepam ___________________________ 2773
(26) Lormetazepam ___________________________ 2774
(27) Mebutamate ___________________________ 2800
(28) Methaqualone ___________________________ 2836
(29) Mephobarbital ___________________________ 2860
(30) Meprobamate ___________________________ 2820
(31) Methohexital ___________________________ 2264
(32) Methylphenobarbital (mephobarbital) ___________________________ 2250
(33) Midazolam ___________________________ 2884
(34) nimetazepam ___________________________ 2837
(35) Nitrazepam ___________________________ 2834
(36) Nordiazepam ___________________________ 2838
(37) Oxazepam ___________________________ 2835
(38) Oxazolam ___________________________ 2839
(39) Paraldehyde ___________________________ 2585
(40) Pethidine (morphine) ___________________________ 2591
(41) Phenobarbital ___________________________ 2285
(42) Pinazepam ___________________________ 2883
(43) Prazepam ___________________________ 2764
(44) Quazepam ___________________________ 2881
(45) Temazepam ___________________________ 2925
(46) Teirazepam ___________________________ 2886
(47) Tranazolam ___________________________ 2887
(48) Zaleplon ___________________________ 2781
(49) Zolpidem ___________________________ 2783

(d) Fenfluramine. Any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

(1) Fenfluramine ___________________________ 1670

(e) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

(1) Cathine (+)-norpseudoephedrine) ___________________________ 1520
(2) Diethylpropion ___________________________ 1610
(3) Fenfluramine ___________________________ 1760
(4) Fenproporex ___________________________ 1575
(5) Mazindol ___________________________ 1605
(6) Mefenterorex ___________________________ 1580
(7) Medafinil ___________________________ 1680
(8) Pemoline (including organometallic complexes and chelates thereof) ___________________________ 1530
(9) Phentermine ___________________________ 1640
(10) Pidopline ___________________________ 1750
(11) Silbutramine ___________________________ 1675
(12) SPA (+)-1-dimethylamin-1,2-diphenylethane) ___________________________ 1635

(f) Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

(1) Pentazocine ___________________________ 9709
(2) Butorphanol (including its optical isomers) ___________________________ 9720

[39 FR 22143, June 20, 1974]
§ 1308.15 Schedule V.

(a) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts, as set forth below:

(1) Buprenorphine .......................................................... 9064

(c) Narcotic drugs containing non-narcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(6) Not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(d) Stimulants. Unless specifically excepted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

(1) Pyrovalerone ................................. 1485.

(2) [Reserved]


EXCLUDED NONNARCOTIC SUBSTANCES

§ 1308.21 Application for exclusion of a nonnarcotic substance.

(a) Any person seeking to have any nonnarcotic substance which may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), be lawfully sold over the counter without a prescription, excluded from any schedule, pursuant to section 201(g) (1) of the Act (21 U.S.C. 811 (g) (1)), may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(b) An application for an exclusion under this section shall contain the following information:

(1) The name and address of the applicant;

(2) The name of the substance for which exclusion is sought; and

(3) The complete quantitative composition of the substance.

(c) Within a reasonable period of time after the receipt of an application for an exclusion under this section, the Administrator shall notify the applicant of his acceptance or nonacceptance of his application, and if not accepted, the reason therefore. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraph (b) of this section. If the application is accepted for filing, the Administrator shall issue and publish in the FEDERAL REGISTER his order on the application, which shall include a reference to the legal authority under which the order is issued and the findings of fact and conclusions of law upon which the order is based. This order shall specify the date on which it
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shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order within 60 days of the date of publication of his order in the Federal Register. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(d) The Administrator may at any time revoke any exclusion granted pursuant to section 201(g) of the Act (21 U.S.C. 811(g)) by following the procedures set forth in paragraph (c) of this section for handling an application for an exclusion which has been accepted for filing.

§ 1308.22 Excluded substances.

The following nonnarcotic substances which may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), be lawfully sold over the counter without a prescription, are excluded from all schedules pursuant to section 201(g) (1) of the Act (21 U.S.C. 811(g) (1)):

<table>
<thead>
<tr>
<th>Company</th>
<th>Trade name</th>
<th>NDC code</th>
<th>Form</th>
<th>Controlled substance (mg or mg/ml)</th>
</tr>
</thead>
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<tr>
<td>Bioline Laboratories</td>
<td>Theophed</td>
<td>00719–1945</td>
<td>TB</td>
<td>Phenobarbital</td>
</tr>
<tr>
<td>Goldline Laboratories</td>
<td>Guiaphed Elixir</td>
<td>00182–1377</td>
<td>EL</td>
<td>Phenobarbital</td>
</tr>
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<td>Goldline Laboratories</td>
<td>Tedigen Tablets</td>
<td>00182–0134</td>
<td>TB</td>
<td>Phenobarbital</td>
</tr>
<tr>
<td>Hawthorne Products Inc</td>
<td>Choate’s Leg Freeze</td>
<td>00071–0230</td>
<td>TB</td>
<td>Phenobarbital</td>
</tr>
<tr>
<td>Parke-Davis &amp; Co</td>
<td>Tedral</td>
<td>00071–0242</td>
<td>EX</td>
<td>Phenobarbital</td>
</tr>
<tr>
<td>Parke-Davis &amp; Co</td>
<td>Tedral Elixir</td>
<td>00071–0231</td>
<td>TB</td>
<td>Phenobarbital</td>
</tr>
<tr>
<td>Parke-Davis &amp; Co</td>
<td>Tedral S.A.</td>
<td>00071–0237</td>
<td>SU</td>
<td>Phenobarbital</td>
</tr>
<tr>
<td>Parmed Pharmacy</td>
<td>Asma-Ese</td>
<td>00349–2018</td>
<td>TB</td>
<td>Phenobarbital</td>
</tr>
<tr>
<td>Rendex Labs</td>
<td>Asma-Aids</td>
<td>00367–3153</td>
<td>TB</td>
<td>Phenobarbital</td>
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<tr>
<td>Smith Kline Consumer</td>
<td>Benzdrex</td>
<td>49692–0928</td>
<td>IN</td>
<td>Propylhexedrine</td>
</tr>
<tr>
<td>Sterling Drug, Inc</td>
<td>Bronkolor</td>
<td>00057–1004</td>
<td>EL</td>
<td>Phenobarbital</td>
</tr>
<tr>
<td>Sterling Drug, Inc</td>
<td>Bronktabs</td>
<td>00057–1005</td>
<td>TB</td>
<td>Phenobarbital</td>
</tr>
<tr>
<td>Vicks Chemical Co</td>
<td>Vicks Inhaler</td>
<td>23900–0010</td>
<td>IN</td>
<td>l-Desoxyephedrine</td>
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<tr>
<td>White Hall Labs</td>
<td>Primatene (P-tablets)</td>
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<td>TB</td>
<td>Phenobarbital</td>
</tr>
</tbody>
</table>


EXEMPT CHEMICAL PREPARATIONS

§ 1308.23 Exemption of certain chemical preparations; application.

(a) The Administrator may, by regulation, exempt from the application of all or any part of the Act any chemical preparation or mixture containing one or more controlled substances listed in any schedule, which preparation or mixture is intended for laboratory, industrial, educational, or special research purposes and not for general administration to a human being or other animal, if the preparation or mixture either:

(1) Contains no narcotic controlled substance and is packaged in such a form or concentration that the packaged quantity does not present any significant potential for abuse (the type of packaging and the history of abuse of the same or similar preparations may be considered in determining the potential for abuse of the preparation or mixture); or

(2) Contains either a narcotic or nonnarcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration, that the preparation or mixture does not present any potential for abuse. If the preparation or mixture contains a narcotic controlled substance, the preparation or mixture must be formulated in such a manner that it incorporates methods of denaturing or other means so that the preparation or mixture is not liable to be abused or have
§ 1308.23

ill effects, if abused, and so that the narcotic substance cannot in practice be removed.

(b) Any person seeking to have any preparation or mixture containing a controlled substance and one or more noncontrolled substances exempted from the application of all or any part of the Act, pursuant to paragraph (a) of this section, may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(c) An application for an exemption under this section shall contain the following information:

(1) The name, address, and registration number, if any, of the applicant;

(2) The name, address, and registration number, if any, of the manufacturer or importer of the preparation or mixture, if not the applicant;

(3) The exact trade name or other designation of the preparation or mixture;

(4) The complete qualitative and quantitative composition of the preparation or mixture (including all active and inactive ingredients and all controlled and noncontrolled substances);

(5) The form of the immediate container in which the preparation or mixture will be distributed with sufficient descriptive detail to identify the preparation or mixture (e.g., bottle, packet, vial, soft plastic pillow, agar gel plate, etc.);

(6) The dimensions or capacity of the immediate container of the preparation or mixture;

(7) The label and labeling, as defined in part 1300 of this chapter, of the immediate container and the commercial containers, if any, of the preparation or mixture;

(8) A brief statement of the facts which the applicant believes justify the granting of an exemption under this paragraph, including information on the use to which the preparation or mixture will be put;

(9) The date of the application; and

(10) Which of the information submitted on the application, if any, is deemed by the applicant to be a trade secret or otherwise confidential and entitled to protection under subsection 402(a)(8) of the Act (21 U.S.C. 842(a) (8)) or any other law restricting public disclosure of information.

(d) The Administrator may require the applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted.

(e) Within a reasonable period of time after the receipt of an application for an exemption under this section, the Administrator shall notify the applicant of his acceptance or nonacceptance of his application, and if not accepted, the reason therefor. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (c) or requested pursuant to paragraph (d) is lacking or is not set forth as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraphs (c) and (d) of this section. If the application is accepted for filing, the Administrator shall issue and publish in the Federal Register his order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order within 60 days of the date of publication of his order in the Federal Register. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(f) The Administrator may at any time revoke or modify any exemption granted pursuant to this section by following the procedures set forth in paragraph (e) of this section for handling an application for an exemption which has been accepted for filing. The Administrator may also modify or revoke the criteria by which exemptions are granted (and thereby modify or revoke all preparations and mixtures granted
§ 1308.24  Exempt chemical preparations.

(a) The chemical preparations and mixtures approved pursuant to §1308.23 are exempt from application of sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003 and 1004 of the Act (21 U.S.C. 822–823, 825–829, 952–954) and §1301.74 of this chapter, to the extent described in paragraphs (b) to (h) of this section. Substances set forth in paragraph (j) of this section shall be exempt from the application of sections 305, 306, 307, 308, 309, 1002, 1003 and 1004 of the Act (21 U.S.C. 822–823, 825–829, 952–954) and §§1301.71—1301.73 and 1301.74 (a), (b), (d), (e) and (f) of this chapter to the extent as hereinafter may be provided.

(b) Registration and security: Any person who manufactures an exempt chemical preparation or mixture must be registered under the Act and comply with all relevant security requirements regarding controlled substances being used in the manufacturing process until the preparation or mixture is in the form described in paragraph (i) of this section. Any other person who handles an exempt chemical preparation after it is in the form described in paragraph (i) of this section is not required to be registered under the Act to handle that preparation, and the preparation is not required to be stored in accordance with security requirements regarding controlled substances.

(c) Labeling: In lieu of the requirements set forth in part 1302 of this chapter, the label and the labeling of an exempt chemical preparation must be prominently marked with its full trade name or other description and the name of the manufacturer or supplier as set forth in paragraph (i) of this section, in such a way that the product can be readily identified as an exempt chemical preparation. The label and labeling must also include in a prominent manner the statement “For industrial use only” or “For chemical use only” or “For in vitro use only—not for human or animal use” or “Diagnostic reagent—for professional use only” or a comparable statement warning the person reading it that human or animal use is not intended. The symbol designating the schedule of the controlled substance is not required on either the label or the labeling of the exempt chemical preparation, nor is it necessary to list all ingredients of the preparation.

(d) Records and reports: Any person who manufactures an exempt chemical preparation or mixture must keep complete and accurate records and file all reports required under part 1304 of this chapter regarding all controlled substances being used in the manufacturing process until the preparation or mixture is in the form described in paragraph (i) of this section. In lieu of records and reports required under part 1304 of this chapter regarding exempt chemical preparations, the manufacturer need only record the name, address, and registration number, if any, of each person to whom the manufacturer distributes any exempt chemical preparation. Each importer or exporter of an exempt narcotic chemical preparation must submit a semianual report of the total quantity of each substance imported or exported in each calendar half-year within 30 days of the close of the period to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Department of Justice, Washington, DC 20537. Any other person who handles an exempt chemical preparation after it is in the form described in paragraph (i) of this section is not required to maintain records or file reports.

(e) Quotas, order forms, prescriptions, import, export, and transshipment requirements: Once an exempt chemical preparation is in the form described in paragraph (i) of this section, the requirements regarding quotas, order forms, prescriptions, import permits and declarations, export permit and declarations, and transshipment and intransit permits and declarations do not apply. These requirements do apply, however, to any controlled substances used in manufacturing the exempt chemical preparation before it is in the form described in paragraph (i) of this section.
§ 1308.25 Exclusion of a veterinary anabolic steroid implant product; application.

(a) Any person seeking to have any anabolic steroid product, which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration, identified as being excluded from any schedule, pursuant to section 102(41)(B)(i) of the Act (21 U.S.C. 802(41)(B)(i)), may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(b) An application for any exclusion under this section shall be submitted in triplicate and contain the following information:

(1) The name and address of the applicant;

(2) The name of the product;

(3) The chemical structural formula or description for any anabolic steroid contained in the product;

(4) A complete description of dosage and quantitative composition of the dosage form;

(5) The conditions of use including whether or not Federal law restricts this product to use by or on the order of a licensed veterinarian;

(6) A description of the delivery system in which the dosage form will be distributed with sufficient detail to identify the product (e.g., 20 cartridge brown plastic belt);

(7) The label and labeling of the immediate container and the commercial containers, if any, of the product;

(8) The name and address of the manufacturer of the dosage form if different from that of the applicant; and

(9) Evidence that the product has been approved by the Secretary of Health and Human Services for administration through implant to cattle or other nonhuman species.

(c) Within a reasonable period of time after the receipt of an application for an exclusion under this section, the
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§ 1308.31  Application for exemption of a nonnarcotic prescription product.

(a) Any person seeking to have any compound, mixture, or preparation containing any nonnarcotic controlled substance listed in §1308.12(e), or in §1308.13 (b) or (c), or in §1308.14, or in §1308.15, exempted from application of all or any part of the Act pursuant to section 201(g)(3)(A), of the Act (21 U.S.C. 811(g)(3)(A). may apply to the Administrator, Drug Enforcement Administration, Washington, DC 20537, for such exemption.

(b) An application for an exemption under this section shall contain the following information:
   (1) The complete quantitative composition of the dosage form.
   (2) Description of the unit dosage form together with complete labeling.
   (3) A summary of the pharmacology of the product including animal investigations and clinical evaluations and studies, with emphasis on the psychic and/or physiological dependence liability (this must be done for each of the active ingredients separately and for the combination product).
   (4) Details of synergisms and antagonisms among ingredients.
   (5) Deterrent effects of the noncontrolled ingredients.
   (6) Complete copies of all literature in support of claims.
   (7) Reported instances of abuse.
   (8) Reported and anticipated adverse effects.


§ 1308.31  Application for exemption of a nonnarcotic prescription product.

(a) Any person seeking to have any compound, mixture, or preparation containing any nonnarcotic controlled substance listed in §1308.12(e), or in §1308.13 (b) or (c), or in §1308.14, or in §1308.15, exempted from application of all or any part of the Act pursuant to section 201(g)(3)(A), of the Act (21 U.S.C. 811(g)(3)(A). may apply to the Administrator, Drug Enforcement Administration, Washington, DC 20537, for such exemption.

(b) An application for an exemption under this section shall contain the following information:
   (1) The complete quantitative composition of the dosage form.
   (2) Description of the unit dosage form together with complete labeling.
   (3) A summary of the pharmacology of the product including animal investigations and clinical evaluations and studies, with emphasis on the psychic and/or physiological dependence liability (this must be done for each of the active ingredients separately and for the combination product).
   (4) Details of synergisms and antagonisms among ingredients.
   (5) Deterrent effects of the noncontrolled ingredients.
   (6) Complete copies of all literature in support of claims.
   (7) Reported instances of abuse.
   (8) Reported and anticipated adverse effects.

§ 1308.32 Exempted prescription products.

The compounds, mixtures, or preparations that contain a nonnarcotic controlled substance listed in §1308.12(e) or in §1308.13 (b) or (c) or in §1308.14 or in §1308.15 listed in the Table of Exempted Prescription Products have been exempted by the Administrator from the application of sections 302 through 305, 307 through 309, 1002 through 1004 of the Act (21 U.S.C. 822–825, 827–829, and 952–954) and §§1301.13, 1301.22, and §§1301.71 through 1301.76 of this chapter for administrative purposes only. An exception to the above is that those products containing butalbital shall not be exempt from the requirement of 21 U.S.C. 952–954 concerning importation, exportation, transshipment and in-transit shipment of controlled substances. Any deviation from the quantitative composition of any of the listed drugs shall require a petition of exemption in order for the product to be exempted. A listing of the Exempted Prescription Products may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537.


EXEMPT ANABOLIC STEROID PRODUCTS

§ 1308.33 Exemption of certain anabolic steroid products; application.

(a) The Administrator, upon the recommendation of the Secretary of Health and Human Services, may, by regulation, exempt from the application of all or any part of the Act any compound, mixture, or preparation containing an anabolic steroid as defined in part 1300 of this chapter if, because of its concentration, preparation, mixture or delivery system, it has no significant potential for abuse (Pub. L. 101–647 section 1903(a)).

(b) Any person seeking to have any compound, mixture, or preparation
containing an anabolic steroid as defined in part 1300 of this chapter exempted from the application of all or any part of the Act, pursuant to paragraph (a) of this section, may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(c) An application for an exemption under this section shall be submitted in triplicate and contain the following information:

(1) The name and address of the applicant;
(2) The name of the product;
(3) The chemical structural formula or description for any anabolic steroid contained in the product;
(4) The complete description of dosage and quantitative composition of the dosage form;
(5) A description of the delivery system, if applicable;
(6) The indications and conditions for use in which species, including whether or not this product is a prescription drug;
(7) Information to facilitate identification of the dosage form, such as shape, color, coating, and scoring;
(8) The label and labeling of the immediate container and the commercial containers, if any, of the product;
(9) The units in which the dosage form is ordinarily available; and
(10) The facts which the applicant believes justify:

(i) A determination that the product has no significant potential for abuse and
(ii) a granting of an exemption under this section.

(d) Within a reasonable period of time after the receipt of the application for an exemption under this section, the Administrator shall notify the applicant of his acceptance or non-acceptance of the application, and if not accepted, the reason therefor. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (c) of this section is lacking or is not set forth so as to be readily understood. The applicant may amend the application to meet the requirements of paragraph (c) of this section. If accepted for filing, the Administrator will request from the Secretary for Health and Human Services his recommendation, as to whether such product which contains an anabolic steroid should be considered for exemption from certain portions of the Controlled Substances Act. On receipt of the recommendation of the Secretary, the Administrator shall make a determination as to whether the evidence submitted or otherwise available sufficiently establishes that the product possesses no significant potential for abuse. The Administrator shall issue and publish in the Federal Register his order on the application, which shall include a reference to the legal authority under which the order is issued, and the findings of fact and conclusions of law upon which the order is based. This order shall specify the date on which it will take effect. The Administrator shall permit any interested person to file written comments on or objections to the order within 60 days of the date of publication of his order in the Federal Register. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(e) The Administrator may revoke any exemption granted pursuant to section 1903(a) of Public Law 101–647 by following the procedures set forth in paragraph (d) of this section for handling an application for an exemption which has been accepted for filing.


§ 1308.34 Exempt anabolic steroid products.

The list of compounds, mixtures, or preparations that contain an anabolic steroid that have been exempted by the Administrator from application of sections 302 through 309 and 1002 through 1004 of the Act (21 U.S.C. 822–829 and 952–954) and §§1301.13, 1301.22, and 1301.71 through 1301.76 of this chapter for administrative purposes only may
§ 1308.41

be obtained by submitting a written re-
quest to the Drug and Chemical Eval-
uation Section, Drug Enforcement Ad-
ministration, Washington, DC 20537.


Hearings

§ 1308.41 Hearings generally.

In any case where the Administrator
shall hold a hearing on the issuance,
amendment, or repeal of rules pursuant
to section 201 of the Act, the proce-
dures for such hearing and accom-
panying proceedings shall be governed
generally by the rulemaking proce-
dures set forth in the Administrative
Procedure Act (5 U.S.C. 551–559) and
specifically by section 201 of the Act (21
U.S.C. 811), by §§ 1308.42–1308.51, and by
§§ 1316.41–1316.67 of this chapter.

§ 1308.42 Purpose of hearing.

If requested by any interested person
after proceedings are initiated pursu-
ant to §1308.43, the Administrator shall
hold a hearing for the purpose of re-
cieving factual evidence and expert
opinion regarding the issues involved
in the issuance, amendment or repeal
of a rule issuable pursuant to section
201(a) of the Act (21 U.S.C. 811(a)). Ex-
tensive argument should not be offered
into evidence but rather presented in
opening or closing statements of coun-
sel or in memoranda or proposed find-
ings of fact and conclusions of law. Ad-
ditional information relating to hear-
ings to include waivers or modification
of rules, request for hearing, burden of
proof, time and place, and final order
are set forth in part 1316 of this chap-
ter.


§ 1308.43 Initiation of proceedings for
rulemaking.

(a) Any interested person may sub-
mitt a petition to initiate proceedings
for the issuance, amendment, or repeal
of any rule or regulation issuable pur-
suant to the provisions of section 201 of
the Act.

(b) Petitions shall be submitted in
quintuplicate to the Administrator in
the following form:

(Date)

ADMINISTRATOR, DRUG ENFORCEMENT
ADMINISTRATION
Department of Justice,
Washington, DC 20537.

DEAR SIR: The undersigned __________
hereby petitions the Administrator to ini-
tiate proceedings for the issuance (amend-
ment or repeal) of a rule or regulation pursuant
to section 201 of the Controlled Sub-
stances Act.

Attached hereto and constituting a part
of this petition are the following:

(A) The proposed rule in the form proposed
by the petitioner. (If the petitioner seeks
the amendment or repeal of an existing rule, the
existing rule, together with a reference to
the section in the Code of Federal Regula-
tions where it appears, should be included.)

(B) A statement of the grounds which the
petitioner relies for the issuance (amend-
ment or repeal) of the rule. (Such grounds
shall include a reasonably concise statement
of the facts relied upon by the petitioner, in-
cluding a summary of any relevant medical
or scientific evidence known to the peti-
tioner.)

All notices to be sent regarding this peti-
tion should be addressed to:

(Name)

(Street Address)

(City and State)

Respectfully yours,

(Signature of petitioner)

(c) Within a reasonable period of
time after the receipt of a petition, the
Administrator shall notify the peti-
tioner of his acceptance or nonaccept-
ance of the petition, and if not accept-
ed, the reason therefor. The Adminis-
trator need not accept a petition for
filing if any of the requirements pre-
scribed in paragraph (b) of this section
is lacking or is not set forth so as to be
readily understood. If the petitioner
desires, he may amend the petition to
meet the requirements of paragraph (b)
of this section. If accepted for filing, a
petition may be denied by the Adminis-
trator within a reasonable period of
time thereafter if he finds the grounds
upon which the petitioner relies are
not sufficient to justify the initiation
of proceedings.
(d) The Administrator shall, before initiating proceedings for the issuance, amendment, or repeal of any rule either to control a drug or other substance, or to transfer a drug or other substance from one schedule to another, or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation and the Secretary’s recommendations as to whether such drug or other substance should be so controlled, transferred, or removed as a controlled substance. The recommendations of the Secretary to the Administrator shall be binding on the Administrator as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Administrator shall not control that drug or other substance.

(e) If the Administrator determines that the scientific and medical evaluation and recommendations of the Secretary and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or additional control over the drug or other substance, or substantial evidence that the drug or other substances should be subjected to lesser control or removed entirely from the schedules, he shall initiate proceedings for control, transfer, or removal as the case may be.

(f) If and when the Administrator determines to initiate proceedings, he shall publish in the Federal Register general notice of any proposed rule making to issue, amend, or repeal any rule pursuant to section 201 of the Act. Such published notice shall include a statement of the time, place, and nature of any hearings on the proposal in the event a hearing is requested pursuant to §1308.44. Such hearings may not be commenced until after the expiration of at least 30 days from the date the general notice is published in the Federal Register. Such published notice shall also include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule, and, in the discretion of the Administrator, a summary of the subjects and issues involved.

(g) The Administrator may permit any interested persons to file written comments on or objections to the proposal and shall designate in the notice of proposed rule making the time during which such filings may be made.


§ 1308.44 Request for hearing or appearance; waiver.

(a) Any interested person desiring a hearing on a proposed rulemaking, shall, within 30 days after the date of publication of notice of the proposed rulemaking in the Federal Register, file with the Administrator a written request for a hearing in the form prescribed in §1316.47 of this chapter.

(b) Any interested person desiring to participate in a hearing pursuant to §1308.41 shall, within 30 days after the date of publication of the notice of hearing in the Federal Register, file with the Administrator a written notice of his intention to participate in such hearing in the form prescribed in §1316.48 of this chapter. Any person filing a request for a hearing need not also file a notice of appearance; the request for a hearing shall be deemed to be a notice of appearance.

(c) Any interested person may, within the period permitted for filing a request for a hearing, file with the Administrator a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(d) If any interested person fails to file a request for a hearing; or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

(e) If all interested persons waive or are deemed to waive their opportunity for the hearing or to participate in the
§ 1308.45 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall cause to be published in the FEDERAL REGISTER his order in the proceeding, which shall set forth the final rule and the findings of fact and conclusions of law upon which the rule is based. This order shall specify the date on which it shall take effect, which shall not be less than 30 days from the date of publication in the FEDERAL REGISTER, unless the Administrator finds that conditions of public health or safety necessitate an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.


§ 1308.46 Control required under international treaty.

Pursuant to section 201(d) of the Act (21 U.S.C. 811(d)), where control of a substance is required by U.S. obligations under international treaties, conventions, or protocols in effect on May 1, 1971, the Administrator shall issue and publish in the FEDERAL REGISTER an order controlling such substance under the schedule he deems most appropriate to carry out obligations. Issuance of such an order shall be without regard to the findings required by subsections 201(a) or 202(b) of the Act (21 U.S.C. 811(a) or 812(b)) and without regard to the procedures prescribed by §1308.41 or subsections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and (b)). An order controlling a substance shall become effective 30 days from the date of publication in the FEDERAL REGISTER, unless the Administrator finds that conditions of public health or safety necessitate an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.


§ 1308.47 Control of immediate precursors.

Pursuant to section 201(e) of the Act (21 U.S.C. 811(e)), the Administrator may, without regard to the findings required by subsection 201(a) or 202(b) of the Act (21 U.S.C. 811(a) or 812(b)) and without regard to the procedures prescribed by §1308.41 or subsections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and (b)), issue and publish in the FEDERAL REGISTER an order controlling an immediate precursor. The order shall designate the schedule in which the immediate precursor is to be placed, which shall be the same schedule in which the controlled substance of which it is an immediate precursor is placed or any other schedule with a higher numerical designation. An order controlling an immediate precursor shall become effective 30 days from the date of publication in the FEDERAL REGISTER, unless the Administrator finds that conditions of public health or safety necessitate an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.


§ 1308.49 Emergency scheduling.

Pursuant to 21 U.S.C. 811(h) and without regard to the requirements of 21 U.S.C. 811(b) relating to the scientific and medical evaluation of the Secretary of Health and Human Services, the Administrator may place a substance into Schedule I on a temporary basis, if he determines that such action is necessary to avoid an imminent hazard to the public safety. An order issued under this section may not be effective before the expiration of 30 days from:

(a) The date of publication by the Administrator of a notice in the FEDERAL REGISTER of his intention to issue such order and the grounds upon which such order is to be issued, and
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(b) The date the Administrator has transmitted notification to the Secretary of Health and Human Services of his intention to issue such order. An order issued under this section shall be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under section 201(a) (21 U.S.C. 811(a)) with respect to such substance or at the end of one year from the effective date of the order scheduling the substance, except that during the pendency of proceedings under section 201(a) (21 U.S.C. 811(a)) with respect to the substance, the Administrator may extend the temporary scheduling for up to six months.


PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS

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SOURCE: 60 FR 32454, June 22, 1995, unless otherwise noted.

GENERAL INFORMATION

§ 1309.01 Scope of part 1309.

Procedures governing the registration of manufacturers, distributors, importers and exporters of List I chemicals pursuant to Sections 102, 302, 303, 1007 and 1008 of the Act (21 U.S.C. 802, 822, 823, 824, 830, 871(b), 875, 877, 958) are set forth generally by those sections and specifically by the sections of this part.

§ 1309.02 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.