

BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter of:

NORTHWOODS DRUG CO., INC.
(Permit No. 3028)

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**CONSENT ORDER OF
DISCIPLINE**

THIS MATTER came on to be considered at a prehearing conference (hereinafter, "Conference") before a member of the North Carolina Board of Pharmacy (hereinafter, "Board") pursuant to 21 N.C.A.C. 46 .2008. This Conference was scheduled for September 19, 2011 and, after appropriate notice, was heard on that day by Board member E. Lazelle Marks at the offices the Board. Respondent Northwoods Drug Co., Inc. (Permit No. 3028) (hereinafter, "Respondent" or "Northwoods") was present through the person of its pharmacist-manager, Gene Herring, and was represented by Counsel George L. Collins. Counsel Clinton R. Pinyan represented the Board. Members of the Board's investigative staff were also present at the Conference.

Respondent has agreed to waive a formal hearing in the above-referenced matter. Both parties stipulate and agree to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By his consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. The North Carolina Board of Pharmacy is a body duly organized under the laws of North Carolina and is the proper body for this proceeding under the authority granted it in

Chapter 90 of the General Statutes of North Carolina, and the rules and regulations promulgated thereunder.

2. Respondent is and was, at all relevant times referred to herein, the holder of Permit No. 3028 from the Board, and located 344 Henderson Drive, Jacksonville, North Carolina. Respondent is and was, at all relevant times referenced to herein, subject to the rules and regulations of the North Carolina Board of Pharmacy and the laws of the State of North Carolina.

3. Respondent's pharmacist-manager is and was, at all relevant times referred to herein, Gene Herring (License No. 5202).

3. In 2010, Respondent failed to maintain accurate and adequate records related to controlled substances, as required by state and federal law, and filled prescriptions for schedule II controlled substances in a fashion prohibited by state and federal law, as set forth more specifically herein.

4. On June 24, 2010, Board investigators performed an inspection at Northwoods (the "June 2010" inspection).

5. During the June 2010 inspection, Respondent could not produce any prior records of required biennial invoices of controlled substances.

6. In addition, during that June 2010 inspection, Board investigators located two prescriptions for schedule II controlled substances that Respondent had partially filled more than 72 hours previously and that Respondent's pharmacist-manager acknowledged that he was planning to complete filling upon receipt of his next shipment of those medications. Those two prescriptions were as follows:

a. A prescription for 120 dosage units of Nucynta 50 mg (Rx # 784652). On June 11, 2010, Respondent dispensed 105 dosage units of the prescribed drug. At the time of the June 2010 inspection, Respondent maintained a printout of the label for this prescription on its counter with the handwritten notation "due 15." Respondent's pharmacist-manager acknowledged to Board investigators that, at the time of the inspection, he had intended to fill the remainder of the prescription, even though it had been partially filled thirteen days before the inspection.

b. A prescription for 30 dosage units of Concerta 54 mg (Rx # 784930). On June 17, 2010, Respondent dispensed 28 dosage units of the prescribed drug. At the time of the June 2010 inspection, Respondent maintained a printout of the label for this prescription on its counter with the handwritten notation "due 2." Respondent's pharmacist-manager acknowledged to Board investigators that, at the time of the inspection, he had intended to fill the remainder of the prescription, even though it had been partially filled seven days before the inspection.

7. During the June 2010 inspection, Respondent's pharmacist-manager told the Board investigators that, on multiple occasions in the past, Respondent had dispensed partial fills of schedule II controlled substances and had subsequently filled the remainder of the prescription more than 72 hours after the original partial fill. Respondent's pharmacist-manager informed the Board investigators that, because of Respondent's financial problems, it often did not have adequate stock on hand to dispense the full amount of prescribed schedule II controlled substances and other drugs.

8. During the June 2010 inspection, the Board investigators warned Respondent that, regardless of its financial circumstances, state and federal law did not permit it to dispense partial

fills of schedule II controlled substances and subsequently fill the remainder of the prescription more than 72 hours after the original partial fill. The Board investigators told Respondent that, in the future, if it dispensed partial fills of schedule II controlled substances and could not fill the remainder of the prescription within 72 hours, its legal alternative would be to refuse to fill the remainder of the prescription and to have the patient secure from the physician a new written prescription for any additional schedule II controlled substances to be dispensed.

9. On November 22, 2010, Board investigators performed another inspection of Northwoods (the "November 2010" inspection).

10. During the November 2010 inspection, Respondent's pharmacist-manager initially stated that, since the June 2010 inspection, Respondent had not dispensed partial fills of schedule II controlled substances and then subsequently filled the remainder of the prescription more than 72 hours after the original partial fill.

10. Upon review of Respondent's records, the Board investigators determined that, after the June 2010 inspection, Respondent in fact had continued to dispense partial fills of schedule II controlled substances and then to subsequently fill the remainder of the prescription more than 72 hours after the original partial fill. After further questioning from the Board investigators, Respondent's pharmacist-manager acknowledged that, after the June 2010 inspection, Respondent had continued to do so on multiple occasions.

11. The Board investigators could not definitely determine the number of times, prior to the November 2010 inspection, that Respondent had dispensed partial fills of schedule II controlled substances and then subsequently filled the remainder of the prescription more than 72 hours after the original partial fill. That difficulty arose from Respondent's maintenance of dispensing records for controlled substances and other drugs that were inaccurate, inadequate

and did not comply with state and federal law. More specifically, on each instance when Respondent dispensed a partial fill of any drug, Respondent maintained a record showing incorrectly that the full prescribed amount of dispensed drugs had been dispensed upon the initial partial fill. For example, on July 9, 2010, Respondent was presented with a prescription (Rx# 785848) for 360 dosage units of Oxycodone 5 mg. Respondent partially filled the prescription with 318 dosage units on July 9, 2010. Nevertheless, Respondent incorrectly recorded in the patient records and on the drug label that it had dispensed all 360 dosage units on July 9, 2010. When Respondent later dispensed the remaining 42 dosage units, it did not record that fact in the patient records and did not create and/or maintain a new drug label when it dispensed the remaining dosage units. This example of improper recordkeeping was repeated with each partial fill of both controlled substances and other drugs.

12. At a minimum, between the June 2010 inspection and the November 2010 inspection, on at least eight (8) occasions, Respondent dispensed partial fills of schedule II controlled substances and then subsequently filled the remainder of the prescription more than 72 hours after the original partial fill. The Board is able to determine that these prescriptions were filled more than 72 hours after the original partial fill because invoices reveal that Respondent did not receive additional shipments of these drugs from its wholesaler until more than 72 hours after the original partial fill. Those prescriptions were Rx numbers 783978, 785848, 786388, 786918, 790678, 791001, 791703 and 791712.

CONCLUSIONS OF LAW

1. All parties are properly before the Board, and the Board has jurisdiction over Respondent and the subject matter of this proceeding.

2. Respondent's conduct, as set out in the findings of fact above, constitutes grounds for discipline pursuant to N.C. Gen. Stat. § 90-85.38 because Respondent's acts were in violation of N.C. Gen. Stat. §§ 90-85.38(b), 90-85.40(b) and (f), 90-106 and 90-108; 21 N.C.A.C. 46 .1804, 46 .2302, and 46 .2502(a); 21 U.S.C. §§ 331, 827, 828, 829, 842 and 843; and 21 C.F.R. §§ 1304.03, 1304.04, 1304.11, 1304.21, 1304.22 and 1306.13.

Based upon the foregoing, and with the consent of the parties, IT IS THEREFORE ORDERED that the permit of Respondent Northwoods Drug Co., Inc. is hereby SUSPENDED for thirty (30) days, which suspension shall be stayed for two years from the date that this Consent Order is accepted by the Board, upon the following conditions:

1. Respondent shall take an inventory of all stocks of controlled substances on hand at least every year. The first annual inventory may be taken on any date which is within one year of the previous biennial inventory taken pursuant to 21 C.F.R. § 1304.11, and future annual inventories may be taken on any date which is within one year of the previous annual inventory. All inventories shall be taken consistent with the requirements of 21 C.F.R. § 1304.11 and other federal laws governing biennial inventories. Each annual inventory shall be provided to the Executive Director of the Board and shall be received by the Executive Director within ten (10) business days of the date that the annual inventory is conducted;

2. Respondent shall cooperate with the Board, its attorneys, investigators and other representatives in any investigation and compliance with the provisions of this Consent Order, and Respondent will be subject to random inspection by the investigators from the Board;

3. Respondent shall violate no laws governing the practice of pharmacy or the distribution of devices or medical equipment;

4. Respondent shall violate no rules and regulations of the Board; and
5. Respondent shall promptly advise the Board of any changes in its pharmacist-manager, as well as any other factors affecting compliance with this Consent Order.

If Respondent fails to comply with any terms or conditions of this Order, Respondent may be subject to additional disciplinary action by the Board. The requirement for an annual inventory shall survive the expiration of the two-year period of the stay of the suspension provided in this Consent Order.

This the 18th day of October, 2011.

NORTH CAROLINA BOARD OF PHARMACY

By: _____


Jay W. Campbell, IV
Executive Director

Northwoods Drug Co., Inc., has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. The undersigned freely, knowingly and voluntarily waives such right by entering into this Final Consent Order. The undersigned understands and agrees that by entering into this Final Consent Order, it certifies that it has read the foregoing Final Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions which may be taken concerning this matter. The undersigned further understands that should it violate the terms and conditions of this Final Consent Order, the Board may take additional disciplinary action. The undersigned understands and agrees that this Final Consent Order will not become effective unless and until approved by the Board. The undersigned understands that it has the right to have counsel of its choice review and advise it with respect to its rights and this Final Consent Order, and represents that it enters this Final Consent Order after consultation with its counsel or after knowingly and voluntarily choosing not to consult with counsel.

The undersigned certifies that its agent executing this Final Consent Order is duly authorized to accept the Final Consent Order on behalf of Northwoods Drug Co., Inc., and to bind the permit holder.

ACCEPTED AND CONSENTED TO BY:

NORTHWOODS DRUG CO., INC.

Gene Herring Date 9-26-2011

By: Gene Herring

Title: President and Pharmacist-Manager

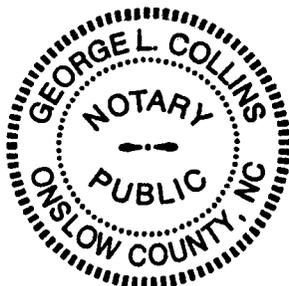
STATE OF N.C.

ONSLOW COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that personally appeared before me this day, and each acknowledged the due execution of the foregoing document: **Gene Herring.**

Date: 9-26-11

George L. Collins
Notary Public



My commission expires: 4-19-14

REJECTED BY:

Date
NORTHWOODS DRUG CO., INC. (Permit No. 3028)