BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter of: STEWART PHARMACEUTICALS, INC. (Permit No. 5373)	)	**CONSENT ORDER**

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 April 14, 2014 and, after appropriate notice, was heard on that day by Board President Gene Minton at the office the Board. Respondent Stewart Pharmaceuticals, Inc. (hereinafter "Respondent" or "the Pharmacy") was present and was represented by counsel Richard Wiggins and Daniel Harrison. Counsel Clinton R. Pinyan represented the Board. Members of the Board's investigative staff and related respondents 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. 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 by its consent. 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 Stewart Pharmaceuticals, Inc., located at 101 Broadfoot Avenue, Fayetteville, North Carolina, is, and was at all relevant times referred to herein, the holder of Pharmacy Permit No. 5373. The Pharmacy and its employees are, and were at all relevant times, subject to the rules and regulations of the North Carolina Board of Pharmacy and the laws of the State of North Carolina.

3. During 2012 and continuing to March 2013, the Pharmacy engaged in the following acts:

a. The Pharmacy failed to provide sufficient oversight and guidance to employees to exercise their responsibilities to ensure safe and accurate compounding of preparations consistent with the required standard of care;

b. The Pharmacy did not compound products for individual patients based upon the presentation of a valid prescription or in anticipation of prescription orders based on established prescribing patterns, or based on a history of receiving valid prescriptions generated within an established practitioner-pharmacist-patient relationship;

c. The Pharmacy compounded and dispensed domperidone;

d. The Pharmacy failed to maintain adequate plans and procedures, training manuals and quality assurance programs to assure the preparation of compounded medication pursuant to practices consistent with the required standard of care;

e. The Pharmacy failed to adequately supervise compounding personnel to assure the safety and integrity of compounding by, among other things, performing and documenting review, assessment and testing of compounding personnel;

f. The Pharmacy failed to maintain facilities and equipment sufficient for the safe and accurate compounding of preparations, and failed to adequately perform and document testing and cleaning of facilities and equipment sufficient for the safe and accurate compounding of preparations;

g. The Pharmacy failed to ensure that personnel used adequate clothing and cleaning processes sufficient for the safe and accurate compounding of preparations;

h. The Pharmacy failed to maintain adequate documentation to assure that preparations were compounded safely and accurately, including but not limited to records of testing, sampling, cleaning, validation and storage and compounding logs;

i. The Pharmacy failed to store hazardous chemicals safely and securely;

j. The Pharmacy failed to establish beyond-use dates consistent with the required standard of care, failed to adequately document the standards used for beyond-use dating, and failed to adequately perform and document potency testing;

k. The Pharmacy used compounding and sterilization practices that did not assure the safe and accurate compounding of preparations and that did not comply with the required standard of care;

l. The Pharmacy failed to perform adequate testing and sampling, and failed to maintain documentation of the same, in order to establish compliance with sterility and toxicity standards sufficient to assure the safe and accurate distribution of compounded preparations;

m. The Pharmacy sent human chorionic gonadotropin (HCG) to another pharmacy for partial processing unlawfully and in contravention of the required standard of care;

n. The Pharmacy mislabeled certain compounded products dispensed to patients by failing to label the proper units dispensed and provide adequate written information on labels;

o. The Pharmacy maintained misbranded drugs and failed to separate expired drugs in the pharmacy stock; and

p. The Pharmacy allowed pharmacists to supervise more technicians than permitted by law.

4. These findings are more specifically described in the following documents that were attached to the Amended Notice of Prehearing Conference, which are incorporated herein by reference, and which describe the nature of the Pharmacy's actions:

a. A Pharmacy Compounding Accreditation Board Survey Report, with accompanying August 3, 2012 cover letter ("PCAB Report");

b. A March 12, 2013 Miscellaneous Inspection Report of the Board of Pharmacy ("Board Inspection");

c. A U.S. Food and Drug Administration ("FDA") Form 483 dated March 25, 2013 ("FDA 483");

d. The Stewart Compounding Pharmacy Report of USP <797> and Standard of Practice Excursions completed by Ken Latta;

e. An FDA Warning Letter dated August 21, 2013 ("FDA Warning Letter").

5. On March 11, 2013, the Board was first provided with the PCAB Report outlining sterile compounding violations found by the Pharmacy Compounding Accreditation Board. That same day, Board investigators commenced an inspection of the Pharmacy. Based on that inspection, later on the same day, the Board members convened in a special meeting and issued a

Summary Order Limiting and Conditioning Permit ("Summary Order"), by which the Board (a) prohibited the Pharmacy from engaging in any sterile compounding and from dispensing any sterile compounded drugs that had been prepared before the Summary Order and (b) required a recall of all sterile compounded drugs prepared on or after February 16, 2013.

6. On or about March 29, 2013, after an inspection by the FDA, the Board and the Pharmacy voluntarily agreed to expand the recall to all sterile compounded drugs that were prepared on or after September 11, 2012, as some of those drugs had beyond-use dates that extended into March 2013.

7. The Pharmacy has not contested any of the violations found by the PCAB, the Board and the FDA, as described in the documents incorporated herein by reference.

8. The Board has received no evidence of any contamination in the Pharmacy's sterile compounded products or injury to any patient. No patient or prescriber has complained to the Board or otherwise reported any issues with any of the Pharmacy's sterile compounded products.

9. The Pharmacy has cooperated with both the recall of the sterile compounded drugs and the Board's investigation.

10. After March 2013, the Pharmacy made significant changes to its planned sterile compounding practices in response to the PCAB Report, the Board Inspection, the FDA 483 and the FDA Warning Letter. On August 21, 2013, the Board investigator and consultant conducted a follow-up inspection of the Pharmacy and reviewed the changed plans for the Pharmacy's sterile compounding practices. In addition, on October 21, 2013, the Board investigator and consultant interviewed the Pharmacy's pharmacist-manager to review his understanding of safe sterile compounding practices and of his responsibility to train and supervise the Pharmacy's

employees. The Board staff's review of the Pharmacy's changes provided evidence to the Board staff that there would be no threat to the public safety, health and welfare if the Pharmacy resumed sterile compounding.

11. On January 21, 2014, the Board entered a Consent Order Terminating in Part the Summary Order Limiting and Conditioning Permit ("the January 2014 Consent Order"). In the January 2014 Consent Order, the Board permitted the Pharmacy to resume engaging in sterile compounding and dispensing, shipping, mailing and delivering sterile compounded products, conditioned upon the Pharmacy's compliance with all requirements of North Carolina law, federal law and the laws of any states in which the Pharmacy is permitted to dispense drugs. Those conditions included, but were not limited to, the requirement that the Pharmacy may compound drugs only based on the existence of a practitioner-pharmacist-patient relationship and the presentation of a valid prescription, or in anticipation of prescription orders based on established prescribing patterns.

12. Since the January 2014 Consent Order, the Pharmacy has been engaged in sterile compounding for nearly three months. There has been no evidence of any threat to the public health, safety and welfare from any sterile compounded products that were prepared after the resumption of sterile compounding in January 2014.

13. Between February 18 and 26, 2014, the FDA performed a follow-up inspection of the Pharmacy. The FDA produced a new Form 483 from this follow-up inspection that noted certain remaining issues with the Pharmacy's operating procedures, practices and documentation related to sterile compounding. The Pharmacy promptly prepared a plan to resolve the remaining issues. At the Conference, the Board President reviewed this February 2014 FDA Form 483, as well as the Pharmacy's plan to resolve the remaining issues, and the Board

President concluded that the findings of the FDA did not require any active restrictions on the Pharmacy's permit, and the Board President was otherwise satisfied that there was no threat to the public health, safety and welfare from the Pharmacy engaging in the practice of pharmacy without active restrictions on its permit.

14. In determining an appropriate resolution of the matter, the Board President further took account of the fact that the Summary Order restricted the Pharmacy's permit for more than ten months, imposing significant constraints on the Pharmacy's practice. The Board President also took account of the fact that the Board's inspection policy requires annual inspections of the Pharmacy, which provides assurances that the Board staff will have an opportunity to continue to review the Pharmacy's compliance with the terms of this Consent Order and with the laws governing the practice of pharmacy and the distribution of drugs.

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 and conclusions of law above, constitutes grounds for discipline pursuant to North Carolina General Statutes § 90-85.38(b) because Respondent's acts were in violation of North Carolina General Statutes §§ 90-85.15A(b) and (c), 90-85.29, 90-85.40(b) and (f), 106-122, 106-133, 106-134 and 106-134.1; 21 NCAC 46 .1601(a), 46 .1804(a), 46 .1805, 46 .1810, 46 .1818, 46 .2501, 46 .2502(a) and (k), 46 .2803, 46 .2804, 46 .2805, 46 .2806 and 46 .2808; 21 U.S.C. §§ 331, 351(a), (b) and (c), 352(b) and (f); and 21 C.F.R. §§ 211.28, 211.42, 211.113, 211.165, 211.166 and 211.167.

3. Respondent admits that the conduct in this matter constitutes sufficient grounds for disciplinary action on its permit under North Carolina General Statutes § 90-85.38(b).

CONCLUSIONS REGARDING DISCIPLINE

Based upon the foregoing Findings of Fact and Conclusions of Law, and with the consent of the Respondent, IT IS THEREFORE ORDERED that:

1. The permit of Respondent Stewart Pharmaceuticals, Inc. (Permit No. 5373) is hereby SUSPENDED for a period of TWO (2) YEARS. The suspension is stayed for a period of FIVE (5) YEARS from the date that this Order is accepted by the Board, upon the following conditions:

a. Respondent shall continue (to the extent not previously completed) the recall of any sterile compounded drugs that were compounded on or after September 11, 2013 and before January 21, 2014. Any recalled products shall be retained and secured;

b. Respondent shall violate no laws governing the practice of pharmacy or the distribution of drugs;

c. Respondent shall violate no rules or regulations of the Board; and

d. Respondent shall cooperate with the Board, its attorneys, investigators, and other representatives in any investigation or inspection.

2. If Respondent fails to comply with any terms or conditions of this Consent Order, the stay of Respondent's suspension shall be terminated and Respondent may be subject to additional disciplinary action by the Board.

3. Except as expressly adopted in this Consent Order, any restrictions in either the Summary Order Limiting and Conditioning Permit (dated March 11, 2013) or the Consent Order

Terminating in Part the Summary Order Limiting and Conditioning Permit (dated January 21, 2014) are hereby TERMINATED.

This the 13th day of May, 2014.

NORTH CAROLINA BOARD OF PHARMACY

By: _____
Jack W. Campbell, IV
Executive Director

Stewart Pharmaceuticals, Inc., the holder of permit number 28305, 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 Consent Order.

The undersigned understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing 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 Consent Order, the Board may take additional disciplinary action.

The undersigned understands and agrees that this 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 Consent Order, and represents that it enters this 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 Consent Order is duly authorized to accept the Consent Order on behalf of Stewart Pharmaceuticals, Inc. and to bind the permit holder.

ACCEPTED AND CONSENTED TO BY:

STEWART PHARMACEUTICALS, INC. (Permit No. ~~28305~~ 05373)

Chalmas Craig Stewart Date 4/21/14

By: CHALMAS CRAIG STEWART

Title: President

STATE OF North Carolina

Cumberland COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the following person personally appeared before me this day and acknowledged the due execution of the foregoing document: Consent Order

Date: 4-21-14

Louise M. Colbourne
Notary Public

Louise M. Colbourne

My commission expires: 01/12/2019

LOUISE M. COLBOURNE NOTARY PUBLIC CUMBERLAND COUNTY, NC

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REJECTED BY:

STEWART PHARMACEUTICALS, INC. (Permit No. 5373)

_____ Date_____

By:_____

Title:_____