

Received
JAN 17 2014
NC Board of Pharmacy

NORTH CAROLINA BOARD OF PHARMACY

In Re:) CONSENT ORDER TERMINATING
) IN PART THE SUMMARY ORDER
STEWART PHARMACEUTICALS, INC.,) LIMITING AND
Permit No. 5373) CONDITIONING PERMIT

THIS MATTER came on to be heard before the North Carolina Board of Pharmacy (the "Board") on January 21, 2014, pursuant to a request by Stewart Pharmaceuticals, Inc. ("Stewart" or "Respondent") to enter this Consent Order Terminating in Part the Summary Order Limiting and Conditioning Permit. After appropriate notice, the matter was heard by Board President Gene Minton and Board Members Dr. J. Parker Chesson, Jr.; Carol Yates Day; E. Lazelle Marks; Robert McLaughlin, Jr., and William A. Mixon at the offices of the North Carolina Board of Pharmacy. Respondent Stewart Pharmaceuticals, Inc. and its counsel, Daniel S. Harrison, were informed of their right to be present at the hearing, in person, and waived that right. Board Counsel Clinton R. Pinyan and members of the Board's investigative and legal staff were present at this hearing.

FINDINGS OF FACT

1. Respondent Stewart Pharmaceuticals, Inc., located at 101 Broadfoot Avenue, Fayetteville, North Carolina, holds permit number 5373.
2. On March 11, 2013, the Board issued a Summary Order Limiting and Conditioning Permit (the "Summary Order") prohibiting Respondent from engaging in any sterile compounding and from dispensing, shipping, mailing or delivering any sterile compounded drugs. That Summary Order also required Respondent to immediately recall any sterile compounded drugs that were compounded on or after February 16, 2013.
3. From March 18 to March 25, 2013, the U.S. Food and Drug Administration ("FDA") conducted an inspection of Respondent's facility. On March 25, 2013, the FDA noted

deficiencies in Respondent's sterile compounding practices on a Form FDA 483 issued to Respondent. And, on August 21, 2013, the FDA issued a Warning Letter to Respondent.

4. Respondent has made changes to its planned sterile compounding practices in response to the FDA's Form FDA 483 and Warning Letter and has described these changes, among other places, in a response to the Warning Letter sent to the FDA on November 20, 2013.

5. Respondent has requested termination of the summary suspension, pending the final disciplinary hearing on the complaint before the Board.

6. Respondent has started the process of seeking an FDA "close-out letter" to secure FDA approval of changes to its compounding practices and has represented that it will continue to pursue that process to conclusion. Board staff has agreed that, given the length of time necessary for that process to conclude and the proposed changes that Respondent has presented to the Board, there are insufficient legal grounds to continue certain limitations of the Summary Order pending a final hearing.

CONCLUSIONS OF LAW

In order to resolve the request for termination of the Summary Order, the Board finds and concludes that it is appropriate to grant the request for termination of the Summary Order, in part, as set forth herein. This conclusion is made solely to resolve the request for termination of the Summary Order. There is no admission, finding or conclusion about the merits of the complaint against Respondent, nor about any discipline that might or might not be appropriate after a final disciplinary hearing.

Based upon the foregoing, and with the consent of the parties, IT IS THEREFORE ORDERED that the request for termination of the Summary Order related to Respondent Stewart Pharmaceuticals, Inc., Permit No. 5373, is GRANTED, in part, as set forth herein:

1. Limitation #1 in the Summary Order is hereby terminated, and Respondent is permitted to resume engaging in sterile compounding and dispensing, shipping, mailing and delivering sterile compounded productions, pending the Board's final hearing on the complaint against Respondent, conditioned upon Respondent's compliance with all requirements of North Carolina law, federal law and the laws of any states in which Respondent is permitted to dispense drugs. Those conditions include, but are not limited to, the requirement that Respondent 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.

2. Limitation #2 in the Summary Order is hereby modified as follows:

Although there is no evidence at this time of any contamination in Respondent's products or injury to any patient, Respondent shall continue (to the extent not previously completed) the recall of any sterile compounded drugs that were compounded on or after February 16, 2013 and before the date of execution of this Order after adoption by the Board. Any recalled products shall be retained and secured.

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

This the 21st day of January, 2014.

NORTH CAROLINA BOARD OF PHARMACY

By: 

Jack W. Campbell, IV
Executive Director

Stewart Pharmaceuticals, Inc., the holder of permit number 5373, 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 Final 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:

Chalmers Craig Stewart Date 1-16-14
Stewart Pharmaceuticals, Inc.
(Permit No. 5373)

NORTH CAROLINA

Cumberland COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the following person(s) personally appeared before me this day, and each acknowledged the due execution of the foregoing document: Chalmers Craig Stewart

Date: January 14, 2014



Cynthia W. Burris
Notary Public
Cynthia W. Burris

My commission expires: 11-29-2018