

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

In the Matter of:

WAKE FOREST DRUG, INC.
(Permit No. 8830)

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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 March 20, 2017 and, after appropriate notice, was heard on that day by Board member Robert A. Graves at the offices the Board. Respondent Wake Forest Drug, Inc. (Permit No. 8830) (hereinafter, "Respondent" or "Wake Forest Drug") was present through its sole owner and pharmacist-manager, Deborah M. Townsend (hereinafter, "Townsend"), and represented by counsel, Crystal S Carlisle. 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. By its 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 Board 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, a pharmacy located at 3113 Rogers Road, Suite 100, Wake Forest, North Carolina and the holder of Permit No. 8830 in the State of North Carolina.

3. In September 2008, Wake Forest Drug and its prior pharmacist-manager began a business relationship with a Raleigh proctologist. Wake Forest Drug began compounding diltiazem gel in large quantities of individual patient vials (but not for specific individual patients) for the proctologist to resell and dispense to patients. Wake Forest Drug later began compounding two additional drugs for the proctologist: a phenol-olive oil combination and a nifedipine gel. The latter two drugs were compounded and sent to the proctologist in large containers for in-office administration. Townsend testified that the prior pharmacist-manager knew that the phenol-olive oil combination was being injected into patients (and therefore was required to be a sterile compound), although Townsend testified that she herself did not know that it was being injected until after this matter was under investigation in April 2015.

4. Until the passage of the Drug Quality and Security Act, under North Carolina law, pharmacists were permitted to compound and dispense drug products only in two circumstances: (1) for individual patients with a prescription, or (2) for practitioners to “obtain compounded drug products to administer to patients.” 21 N.C.A.C. 46 .1810 (former regulation).

5. In early 2011, the Board investigated Wake Forest Drug for compounding the diltiazem other than for individual patients with a prescription, but instead to sell to the proctologist to resell.

6. On July 31, 2012, the Board sent a letter of warning to Wake Forest Drug about its prior compounding of diltiazem for the proctologist. The letter of warning said that Wake Forest Drug had violated the law by providing the diltiazem “in bulk amounts for resale.” The letter of warning went on to say that the cream could be compounded for “office use only,” and that “it is negligent for a pharmacy to provide compounded products to a physician’s office without engaging in reasonable due diligence to ensure such products are in fact only being administered in the office.”

7. Notwithstanding this warning, through March 2015, Wake Forest Drug continued to compound diltiazem in large amounts in individual patient vials (but not for specific individual patients) to provide to the proctologist. The proctologist no longer resold the diltiazem but instead administered a portion of the drug in the office and provided the remainder to the patient to take home. The vials that were dispensed to patients lacked required information, including directions for administration, discard dates and identification of the dispensing pharmacist. Townsend and Wake Forest Drug knew that the proctologist was providing the vials for the patients to take out of the office, but they continued to provide them until March 2015. When the Board investigated in April 2015, the proctologist still had about fifty (50) individual vials left from the most recent compounding.

8. Moreover, from July 29, 2011 to March 2015, Townsend and Wake Forest Drug compounded the phenol-olive oil combination, which was injected into patients and therefore was required to be compounded in sterile conditions, without complying with many of the

requirements for sterile compounding. Townsend testified that she was not aware that the phenol-olive oil combination was being injected, and the Board credits that explanation. However, it was unreasonable and negligent for Townsend not to know how the phenol-olive oil combination was being used, particularly in that (a) Townsend's predecessor pharmacist-manager and former co-owner knew that the combination was being injected (according to Townsend), and (b) Wake Forest Drug failed to label the phenol-olive oil combination with directions as required by law and, if it had, its pharmacists would have been required to inquire about the method of administration. Wake Forest Drug recalled the phenol-olive oil compound. The Board's investigation did not reveal any complaints of patient harm from the use of the improperly compounded combination.

9. When Drug Quality and Security Act was passed, it altered previous law and made it unlawful for pharmacies to compound for office administration (unless they met other federal standards that Wake Forest Drug did not meet). Townsend testified that she did not keep abreast of the passage of the Drug Quality and Security Act at the time of its passage or, otherwise, she would have known that it prohibited Wake Forest Drug from compounding drugs for office administration. Townsend also testified that, when she later learned of the requirements of the Drug Quality and Security Act, she began researching how Wake Forest Drug might continue to supply compounded drugs to the proctologist consistent with the law. But she testified that, while she was performing that research, Wake Forest Drug decided to continue supplying the compounded drugs to the proctologist until March 2015, even though she knew it was unlawful under both the Drug Quality and Security Act and revised North Carolina law.

10. Wake Forest Drug either did not make all required compounding logs or did not maintain them in a fashion that they could be readily provided to Board investigators as required by law. Only a small handful of compounding logs were provided to the Board investigators, and many of them lacked information required by law, such as verifying pharmacist identification.

CONCLUSIONS OF LAW

Based on the above findings, the Board concludes as a matter of law:

1. Respondent violated N.C. Gen. Stat. §§ 90-85.29, 90-85.38(b), 90-85.40(b) and (f), 106-122, 106-133, 106-134 and 106-135; 21 N.C.A.C. 46 .1801, 46 .1804(a), 46 .1810 (former regulation), 46 .2301, 46 .2302, 46 .2501, 46. 2504, 46. 2801, 46 .2803 (former regulation), 46. 2804 (former regulation), 46. 2806 (former regulation) and 46. 2808 (former regulation); 21 U.S.C. §§ 331, 351, 352, 353, 353a and 355; 21 C.F.R. §§ 201.1, 201.5, 201.10, 201.15, 201.17, 201.18, 201.50, 201.51, 201.55, 201.56, 201.57, 211.22, 211.25, 211.28, 211.42, 211.46, 211.48, 211.56, 211.58, 211.63, 211.65, 211.67, 211.80, 211.84, 211.87, 211.100, 211.101, 211.103, 211.105, 211.110, 211.113, 211.122, 211.125, 211.130, 211.134, 211.137, 211.142, 211.150, 211.160, 211.165, 211.166, 211.167, 211.170, 211.180, 211.182, 211,184, 211.186, 211.188, 211.192, 211.194 and 211.196.

2. Respondent admits that the conduct in this matter constitutes sufficient grounds for disciplinary action on its permit under N.C. Gen. Stat. § 90-85.38.

Based upon the foregoing, and with the consent of the parties, IT IS THEREFORE ORDERED that the permit of Respondent Wake Forest Drug, Inc. is hereby SUSPENDED for

ONE (1) WEEK. That suspension is hereby STAYED for a period of ONE (1) YEAR, provided that Respondent complies with the following conditions:

1. Respondent shall violate no laws governing the practice of pharmacy or the distribution of drugs, medical devices or medical equipment; and

2. Respondent shall violate no rules or regulations of the Board.

Respondent shall cooperate with the Board, its attorneys, investigators and other representatives in any investigation and compliance with the provisions of this Consent Order, which cooperation shall include but shall not be limited to and unannounced inspections and audits.

If Respondent fails to comply with any terms or conditions of this Order, the period of stay described above shall be lifted and the Board shall activate the stayed suspension of Respondent's permit and may impose additional discipline.

This the 18th day of April, 2017.

NORTH CAROLINA BOARD OF PHARMACY

By: 

Jay W. Campbell, IV
Executive Director

Wake Forest Drug, Inc., the holder of permit number 8830, 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 Wake Forest Drug, Inc. and to bind the permit holder.

ACCEPTED AND CONSENTED TO BY:



WAKE FOREST DRUG, INC.
(Permit No. 8830)

Deborah M. Townsend Date 4-14-17

By: Deborah M. Townsend
Title: President

STATE OF NORTH CAROLINA

WAKE 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: Deborah M. Townsend.

Date: April 14, 2017

Travis Barkley
Notary Public
TRAVIS BARKLEY

My commission expires: FEB 15, 2022

REJECTED BY:

WAKE FOREST DRUG, INC.
(Permit No. 8830)

_____ Date _____

By: Deborah M. Townsend
Title: President