

BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter of:

BRYAN DRUGS, INC.

(Permit No. 3938)

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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 January 5, 2016 and, after appropriate notice, was heard on that day by Board Member Robert A. Graves at the office of the Board. Respondent Bryan Drugs, Inc. (hereinafter "Respondent" or "the Pharmacy") was present through its owner and current pharmacist-manager, Harrel D. Bryan. 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 Bryan Drugs, Inc., located at 421 Main Street, Tarboro, North Carolina, is, and was at all relevant times referred to herein, the holder of Pharmacy Permit No. 3938. 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. Between March 20 and April 17, 2015, on six (6) occasions, the Pharmacy engaged in wholesale shipments into the states of Mississippi, New Jersey, Texas and Virginia, without having the required non-resident permits. In addition, the Pharmacy shipped some of these drugs in opened, partial packages, which was not permitted by some or all of these states. The Pharmacy made these shipments by using services provided by MatchRx to pair interested buying and selling pharmacies for overstocked prescription drugs. Similar services are provided by other companies, including RxCherryPick, RxTrade and ExchangeMeds. In using the MatchRx service, the Pharmacy relied upon representations that the Pharmacy could lawfully ship to other states using the service. The Pharmacy's representatives acknowledged that they should have researched permitting requirements in other states before shipping there, rather than relying upon MatchRx's representations. Although the Board finds that it was not reasonable for the Pharmacy to rely on the representations of a third-party with a profit motive to cause the Pharmacy to use the service, rather than researching legal requirements on its own, the Board finds that the Pharmacy acted in good faith in its reliance.

4. On April 27, 2015, the Arizona Board of Pharmacy sent a cease and desist letter to another location owned by Bryan Drugs, Inc., requesting that the sister pharmacy cease

shipments into Arizona without a permit. The Arizona Board of Pharmacy sent similar letters to a number of other North Carolina pharmacies. The states into which the Pharmacy had shipped (Mississippi, New Jersey, Texas and Virginia) had similar permitting requirements with which the Pharmacy had not complied. Upon the sister pharmacy's receipt of this letter, the Pharmacy immediately stopped using the MatchRx service and fully cooperated with the Board's investigation of MatchRx shipments.

5. Although the Pharmacy cooperated completely with the Board's investigation of its shipments through MatchRx, the Board is unable to accurately find the full scope of shipments made to other states because MatchRx refused to cooperate fully with the Board's investigation.

6. When an inspection was conducted on August 19, 2015, the Board investigator found a number of violations of the North Carolina Pharmacy Practice Act and its regulations, including:

- a. The Pharmacy maintained in the dispensing stock several drugs that had expired as early as 2011;
- b. The Pharmacy lacked adequate written policies and procedures for the destruction or disposal of adulterated, misbranded, expired and unwanted drugs;
- c. The Pharmacy failed to keep separate prescription files for Schedule II medications;
- d. The Pharmacy failed to obtain and review certificates of analysis for all bulk APIs used for compounding;
- e. The Pharmacy failed to segregate hazardous bulk components for compounding;
- f. The Pharmacy applied beyond-use dates to compounding products that failed to comply with USP <795> and <797> standards, without appropriately securing valid stability information supporting the beyond-use dates and without documenting the circumstances for extending those

beyond-use dates, and further set a number of inappropriate and unlawful beyond-use dates for compounded products;

- g. The Pharmacy maintained inadequate and inconsistent master formulation records for compounding products;
- h. The Pharmacy maintained inadequate and unlawful compounding logs and records in a number of respects;
- i. The Pharmacy failed to adequately document the results of quality control procedures;
- j. The Pharmacy failed to have the powder containment hood certified or tested on an appropriate schedule;
- k. The Pharmacy failed to have hood prefilters checked and replaced regularly;
- l. The Pharmacy failed to make available appropriate protective attire for compounding;
- m. The Pharmacy failed to document that adequate temperature and humidity monitors were maintained;
- n. The Pharmacy failed to document adequate training of personnel in a number of required areas;
- o. The Pharmacy failed to calibrate scales, balances and other equipment for measurement annually;
- p. The Pharmacy failed to adequately assess finished preparations in a number of respect, to document the same, and to set policies and procedures for doing so; and
- q. The Pharmacy failed to provide adequate labels for compounded drugs.

7. The Board has received no evidence of any contamination in the Pharmacy's 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 compounded products.

8. Since the inspection, the Pharmacy has cooperated with the Board's efforts to ensure compliance with all applicable laws governing compounding and documentation. This

cooperation includes voluntarily stopping all compounding, other than simple, non-sterile compounding.

9. As substantial mitigating factors in this case, the Board has considered the Pharmacy's cooperation with the investigation, its immediate compliance with its obligations not to ship without wholesale permits (once it was alerted to those requirements), and its efforts to promptly remedy compounding and documentation deficiencies.

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 21 N.C.A.C. 46 .2502(k), .2801 and .3001, 21 U.S.C. § 353(e); 21 C.F.R., Part 205 and 1304.04; Miss. Code Ann. § 73-21-105; Miss. Code R. § 30-030-3001; N.J. Stat. Ann. § 24:6B-1; N.J. Admin. Code §§ 8:21-3A.4, 8:21-3A.5 and 8:21-3A.12; Tex. Health & Safety Code §§ 431.402, 431.406; 25 Tex. Admin. Code § 229.424; Va. Code Ann. § 54.1-3435.01; and 18 Va. Admin. Code § 110-50-110.

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 Bryan Drugs, Inc. (Permit No. 3938) is hereby REPRIMANDED.

2. The permit of Respondent is further hereby restricted so that Respondent is permitted only to engage in simple, non-sterile compounding. All sterile compounding and all moderate and complex non-sterile compounding by the Respondent is hereby prohibited.

This the 19th day of January, 2016.

NORTH CAROLINA BOARD OF PHARMACY

By:



Jack W. Campbell, IV
Executive Director

Bryan Drugs, Inc., the holder of permit number 3938, 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 Bryan Drugs, Inc. and to bind the permit holder.

ACCEPTED AND CONSENTED TO BY:

BRYAN DRUGS, INC. (Permit No. 3938)

Harrel D. Bryan Date 01/12/2016

By: Harrel D. Bryan

Title: Pharmacist-Manager

STATE OF North Carolina

Edgecombe 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: Harrel D. Bryan.

Date: 1-12-16

Terry B. [Signature]
Notary Public

My commission expires: 9/28/16

REJECTED BY:

BRYAN DRUGS, INC. (Permit No. 3938)

_____ Date _____

By: Harrel D. Bryan

Title: Pharmacist-Manager