AGREED BOARD ORDER #H-16-006-B

RE: IN THE MATTER OF GREENPARK COMPOUNDING PHARMACY (PHARMACY LICENSE #14713)

BEFORE THE TEXAS STATE BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 14713 issued to Greenpark Compounding Pharmacy (Respondent), 4061 F Bellaire Boulevard, Houston, Texas 77025.

By letter dated August 17, 2016, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

> Sections 565.001(a)(1), (2), (12) and (13); 565.002(a)(3) and (6); and 568.003(a)(1), (7) and (10) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2015);
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> Sections 281.7(a)(12), (13) and (29)(A); 281.8(b)(4)(A); 281.9(b)(3); 291.31(1), (15), (16) and (17); 291.32(c)(1)(E) and (F); 291.32(c)(2)(D); 291.131(b)(3); 291.131(c)(2)(B) and (C); 291.131(c)(3)(C); 291.131(d)(8)(E); 291.131(d)(9)(B); 291.131(e)(2)(B)(ii)(VIII); and 295.3(b) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2015); and
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> Sections 431.021(a), (b) and (r); and 431.112(a)(1) of the Texas Food, Drug, and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. (2015), in that allegedly:

COUNTS

On or about September 4, 2015, a pharmacist of Greenpark Compounding Pharmacy, 4061 F Bellaire Boulevard, Houston, Texas 77025, failed to verify or incorrectly verified the correct identity of an ingredient used in compounding a batch preparation, in that lorazepam was used in the preparation of a compounded batch preparation calling for lansoprazole. The compounded batch preparation was assigned lot number 09042015@20, and was labeled 480 ml lansoprazole 3mg/ml suspension. Subsequently, three pediatric patients were dispensed prescriptions from the batch preparation, as follows:

(1) On or about September 8, 2015, the pharmacy dispensed 40 ml of the preparation to patient J.N. The prescription bottle was labeled lansoprazole 3mg/ml suspension with directions to "take 1ml (3mg) by mouth every day." The prescription was assigned prescription number 249233.

(2) On or about September 8, 2015, the pharmacy dispensed 140 ml of the preparation to patient S.B. The prescription bottle was labeled lansoprazole 3mg/ml suspension with directions to "take 2.5 ml (7.5 mg) by mouth every day for 8 weeks." The prescription was assigned prescription number 249234.

(3) On or about September 10, 2015, the pharmacy dispensed 300 ml of the preparation to patient S.P. The prescription bottle was labeled 300 ml lansoprazole 3mg/ml suspension with directions to "give 2.5 ml (7.5 mg) by mouth every day." Patient S.P. was given the medication and received emergency treatment in a hospital after experiencing adverse effects, including drowsiness, lack of coordination and irritability. The prescription was assigned prescription number 246935.

On or about September 16, 2015, two samples of the compounded preparation were analyzed, and the results indicated that the samples contained lorazepam (measured at 2.38 mg/ml and 1.28 mg/ml) and did not contain lansoprazole.

(4) On or about September 4, 2015, Cindy Lee Rodriguez, while acting as an employee (pharmacy technician) of Greenpark Compounding Pharmacy, 4061 F Bellaire Boulevard, Houston, Texas 77025, failed to keep and maintain complete and accurate compounding records for lot number 09042015@20 previously described. Specifically, Ms. Rodriguez forged the initials "R.P.," indicating Ranjeet Patel, a pharmacy technician, on the compounding preparation worksheet as having performed in process checks, when Mr. Patel did not do so.

An informal conference was held in the Board's office on October 4, 2016, with Kenneth Lee Hughes, R.Ph., Pharmacist-in-Charge and President of Prescription Labs, Inc., on behalf of Respondent; and Michele Quattlebaum, Legal Counsel for Respondent, in attendance. The informal conference was heard by a Board panel comprised of: Jenny Downing Yoakum, R.Ph., Board Member; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Kerstin Arnold, General Counsel. Megan Holloway, Staff Attorney, was also in attendance.

By appearing at the informal conference and by signing this Order, Kenneth Lee Hughes, and Respondent's counsel neither admit nor deny the truth of the matters previously set out in this Order, and agree that the Board has jurisdiction in this matter and waive the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent's license shall be placed on probation for a period of two (2) years, with such period to commence thirty (30) days after the entry of this Order. During the period of probation, Respondent shall abide by the terms of this Order, and shall not violate any pharmacy or drug statute or rule of this state, another state, or the United States with respect to pharmacy, controlled substances, and dangerous drugs.

(2) Respondent shall pay a probation fee of one thousand two hundred dollars ($1,200) due one hundred twenty (120) days after the entry of this Order.

(3) Respondent shall pay an administrative penalty of one thousand dollars ($1,000) due one hundred twenty (120) days after the entry of this Order.

(4) Respondent shall develop and implement policies and procedures for a Continuous Quality Improvement Program for purposes of preventing and handling dispensing errors. The Continuous Quality Improvement Program shall include pharmacist peer review in compliance with guidelines approved by Board staff. In addition, the policies and procedures for pharmacist peer review shall state that:

(a) The peer review committee will:

- review incident reports;
- determine what caused errors;
- make recommendations to correct the problem that caused the errors; and
- monitor the changes to determine if the changes have improved the operation of Respondent and reduced errors.

(b) The peer review committee must be comprised of at least two employees of Respondent, including the pharmacist-in-charge and other pharmacist(s) or personnel who are employees of Respondent. The committee shall not be solely comprised of a district or regional manager/supervisor and the pharmacist-in-charge and shall not be used for personnel evaluation purposes.

(c) The peer review committee will meet regularly, and no less than quarterly.

(d) The peer review committee will make a record indicating:

- date of meeting
- location of meeting;
- names of persons attending the meeting;
- description of activities;
- discussion of problems in Respondent's operation (e.g., work flow, dispensing process);
- findings;

- description of recommendations; and
- review of actions or changes relating to individuals, systems, or processes made as a result of previous recommendations.

(5) Respondent shall submit a report and/or documentation of such policies and procedures to Board staff within one hundred twenty (120) days after the entry of this Order. Copies of forms used by Respondent to collect the data on errors committed at the pharmacy (i.e., incident report forms) must be submitted to Board staff, as well as any other peer review forms that have been developed by Respondent. Additionally, records of the peer review committee, as described in subparagraph (d) above, shall be maintained for two (2) years at the location of Respondent and made available for inspection by Board employees.

(6) Respondent shall be responsible for all costs relating to compliance with the requirements of this Order.

(7) Respondent shall allow Board staff to directly contact Respondent on any matter regarding the enforcement of this Order.

(8) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2015), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2016).

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 1st day of November, 2016.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Kenneth Lee Hughes, R.Ph., President of Prescription Labs, Inc.
For and on behalf of Greenpark Compounding Pharmacy

Michele Quattlebaum, Legal Counsel for Greenpark Compounding Pharmacy
Spratt Newsom Law Firm
2211 Norfolk, Suite 1150
Houston, Texas 77098

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy