

Date: December 8, 2021

Permit No.: Unlicensed

Names: Prescription Labs DBA Greenpark Compounding Pharmacy

Address: 4061-F Bellaire Boulevard, Houston, TX 77025

Authority for this Action

Business and Professions Code Section 4316, subdivision (a), states, "The board, through its executive officer, is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure without obtaining that licensure."

Subdivision (b) of that section provides that, whenever the board issues a cease and desist order, the Board must immediately issue the facility a notice setting forth the acts or omissions with which it is charged, specifying the pertinent code section or sections and any regulations.

Activities under this chapter that require licensure include those set forth in the following regulations:

Business and Professions Code (B&PC) section 4112(a) states any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy. B&PC 4112(b) states a person may not act as a nonresident pharmacy unless he or she has obtained a license from the board.

B&PC section 4127(a) states a pharmacy that compounds sterile drug products shall possess a sterile compounding pharmacy license as provided in this article. B&PC section 4127.2(a) states a nonresident pharmacy shall not compound sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable

Acts or Omissions Upon Which this Action is Based

Prescription Labs DBA Greenpark Compounding Pharmacy located at 4061-F Bellaire Boulevard Houston, TX 77025 is not licensed in California by the Board.

On 9/17/21, the Food and Drug Administration (FDA) sent out a MedWatch regarding: "TOPIC: Compounded Products Intended to be Sterile by Greenpark Compounding Pharmacy: CDER Alert - FDA Alerts Patients and Health Care Professionals Not to Use." The FDA stated "...FDA investigators recently inspected Greenpark Compounding Pharmacy's facility during July and

August 2021 and observed conditions which could cause the compounded drugs to be contaminated or otherwise pose risks to patients.

On August 18 and August 31, 2021, the compounder initiated a recall of several lots of a compounded ophthalmic drug. On September 2, 2021, FDA recommended Greenpark Compounding Pharmacy expand its recall to all unexpired compounded drugs intended to be sterile and stop sterile production until it implements adequate corrective actions. To date, the company has refused to recall all unexpired compounded drug products intended to be sterile or to cease compounding of all sterile drugs.

Patients who have received compounded drugs produced by Greenpark Compounding Pharmacy and have concerns should contact their health care professional.”

On 9/30/21, the FDA updated the MedWatch alert to include animal products.

On or about 11/23/21, the Board received recording showing Prescription Labs DBA Greenpark Compounding Pharmacy shipped, mailed, or delivered, in any manner of controlled substances and dangerous drugs into California. Records show this unlicensed activity took place from on or about 9/20/19 to on or about 9/16/21 for approximately 61 prescriptions. Additionally, records showed compounding of sterile drug products for shipment into California. Records show this unlicensed activity took place from on or about 9/20/19 to on or about 9/16/21 for at approximately 52 prescriptions for compound sterile drug products.

Prescription Labs DBA Greenpark Compounding Pharmacy required a license issued by the California Board of Pharmacy under B&PC 4112(b) before doing business as a nonresident pharmacy and under B&PC 4127.2(a) before doing business as a nonresident sterile compounding pharmacy.

As of 12/1/21, three request records (one verbal and two in writing) have been made to Pharmacist Kenneth Hughes of Prescription Labs DBA Greenpark Compounding Pharmacy; however, Pharmacist Hughes has been unwilling to provide any records.

Order

On the basis of the foregoing, the Board, through its Executive Officer, therefore ORDERS:

Effective immediately, Prescription Labs DBA Greenpark Compounding Pharmacy, an unlicensed nonresident pharmacy and an unlicensed nonresident sterile compounding pharmacy, shall cease and desist practicing any activity under this chapter that requires licensure, including compounding sterile drug products for shipment into California, and shipping, mailing, or delivering, in any manner, controlled substances and dangerous drugs into California.

Unlicensed Entity's Right to be Heard and Procedure

Pursuant to Business and Professions Code Section 4316, subdivision (c), within 15 days of receipt of this notice, Prescription Labs DBA Greenpark Compounding Pharmacy may request a hearing before the president of the Board to contest this cease and desist order. Any contest of the cease and desist order will comply with the requirements of Section 11425.10 of the Government Code, a copy of which is enclosed. Chapter 5 of the Administrative Procedures Act (commencing at Government Code Section 11500) does not apply to this proceeding. The hearing will be held no later than five (5) days from the date the owner's request for a hearing is received by the Board. The president will render a written decision within five (5) days of the hearing. In the absence of the president of the Board, the vice president of the Board may conduct the hearing as permitted by this subdivision. Review of the decision of the president of the Board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.

California State Board of Pharmacy

By: Anne Sodergren, Executive Officer

Date: December 8, 2021