California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Date: June 23, 2025
Permit No.: NRP1963 NSC101082
Names: Boothwyn Pharmacy LLC
Address: 221 Gale Ln Kennett Square, PA 19348

Authority for this Action:

Business and Professions Code Section 4127.3, subdivision (a), states, "whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding sterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from compounding sterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier. "Subdivision (b) of that section provides that, whenever the board issues a cease and desist order, the Board must immediately issue the owner a notice setting forth the acts or omissions with which it is charged, specifying the pertinent code section or sections and any regulations.

Acts requiring a Cease and desist to protect public health or safety

On April 24, 2025, during the annual renewal inspection it was noted that two lots of a non-sterile to sterile compounded drug preparations (CSPs) were dispensed and shipped to California patients before the required bacterial endotoxin testing (BET) were received and found to be within allowable limits. When the results were received the BET level exceeded the limits by 2-3 times or more. Boothwyn was unable to provide any documentation that the California patients were notified of these testing failures or that a recall was conducted to get the non-conforming lots out of circulation. To compound these issues, many of the CSPs were labeled as "keep frozen" when in fact Boothwyn failed to have any data to support the CSPs or their container closers would be stable when frozen or that the CSPs would arrive in California in a frozen state. This data is required under the minimum practice standards of the United States Pharmacopeia (USP) Chapter <797> (2022) standards.

After the inspection it was revealed that end product data for at least 7 different lots of CSPs provided by Boothwyn, falsely represented they met end product testing requirements when they did not.

On or about April 28, 2025, former Pharmacist-in-Charge (PIC) who is now the director of the Sterile lab, RPH Matin Farrell represented that the concerns of the California Board of Pharmacy would be addressed and that he was the individual responsible for the falsification of the end product testing results.

From at least May 12, 2025, to June 9, 2025, the Federal Food and Drug Administration (FDA) conducted a follow up inspection (previous inspection was conducted from September 23, 2024, to October 22, 2024), and issued a Form 483 listing 6 observations. The first observation was that Boothwyn had released CSPs that failed to meet the requirement for strength, purity or quality. The FDA cited eleven (11) different lots of non-sterile to sterile CSPs in addition to the two lots observed by the California Board inspector on April 24, 2025. The FDA's second observation was related to the "store frozen" label on CSPs where Boothwyn had no studies to ensure the products were stable under this storage condition.

On or about June 9, 2025, the FDA issued a warning letter to Boothwyn related to their inspection conducted on September 23, 2024, to October 22, 2024. This warning letter states that Boothwyn produced and distributed, adulterated and misbranded animal drugs in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FDA specifically mentioned compounding of unapproved new animal drugs and drug quality violations. The conclusion of the FDA warning letter stated, "All of the animal drugs you produce from BDS (bulk drug substances) violated the FD&C Acts' requirements for approval/indexing, adequate directions for use, and CGMP. "

Boothwyn has shipped both human and animal CSPs into California while using these practices as identified by the FDA and the California Board's inspection. As of June 23, 2025, Boothwyn has failed to provide any evidence to support that they have updated any of their practices to ensure that only safe and effective produces are shipped into California. Recently, Boothwyn compounded a batch of ophthalmic drops which failed potency after approximately 30 days, yet they failed to notify any patients or providers of this failure and no recall has been initiated. These products are still within their expiration date, and patients and providers may be administering these products without any knowledge of this failure.

Based on the continued practice of dispensing and shipping CSPs which failed to meet the requirement for strength, purity or quality, specifically BET level, sterility and/or potency and compounded by the fact that the currency director of the sterile lab has admitted to falsely representing end product data, the patients of California are at high risk of being harmed by the practices at Boothwyn that violation California and federal law and regulation.

Order

On the basis of the foregoing, the Board, through its Executive Officer therefore ORDERS: Effective immediately, Boothwyn, NRP1963/NSC101082, shall immediately cease and desist from compounding sterile drug products for shipment into California.

Entity's Right to be Heard and Procedure

Pursuant to Business and Professions Code Section 4127.3, subdivision (c), within 15 days of receipt of this notice, Boothwyn Pharmacy LLC 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 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

Signed: Sodergren, Anne@DCA Digitally signed by Sodergren, Anne@DCA Date: 2025.06.23 10:14:39 -07'00'

Date:

Acknowledgement

I hereby acknowledge receipt of the above cease and desist order and notice.

By:

Date:

Please return this signed and acknowledged document to the Board of Pharmacy by fax to 916-574-8618 or via email to Christine.acosta@dca.ca.gov.