

IN THE MATTER OF	*	BEFORE THE
ANDERSON COMPOUNDING	*	MARYLAND STATE
PHARMACY	*	BOARD OF PHARMACY
PERMIT NO. P06449	*	Case No. 21-144

* * * * *

PRE-CHARGE CONSENT ORDER

Background

Between March 25, 2019 and April 5, 2019, the U.S. Food and Drug Administration (“FDA”) inspected non-sterile and sterile compounding operations at Anderson Compounding Pharmacy, Inc. (the “Pharmacy”). At the conclusion of the inspection, FDA issued an FDA Form 483 which set forth observations related to sterile compounding operations at the Pharmacy. On April 2, 2019, the Pharmacy voluntarily recalled compounded sterile products out of an abundance of caution. At the same time, the Pharmacy informed FDA that it had ceased all sterile compounding operations and did not intend to resume. The Maryland Board of Pharmacy (the “Board”) received notification from the FDA that it issued a Warning Letter on January 13, 2020 to the Pharmacy which recited the observations in the FDA Form 483. The FDA acknowledged in the Warning Letter that the Pharmacy ceased sterile compounding operations and did not intend to resume. The FDA further requested that the Pharmacy notify FDA if it decided to resume sterile compounding operations.

In lieu of instituting formal proceedings against Anderson Compounding Pharmacy, Inc. in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health

Occ. § 12-101 *et seq.*, the Board and Anderson Compounding Pharmacy, Inc., have agreed to resolve this matter as set forth in this Pre-Charge Consent Order.

FINDINGS OF FACT

1. Anderson Compounding Pharmacy, Inc., is a pharmacy located in Bristol, Tennessee, holding non-resident permit number P06449.
2. From March 26 to April 5, 2019, the FDA conducted an inspection of the Pharmacy's non-sterile and sterile compounding operations. At the conclusion of the inspection, the FDA issued an FDA Form 483 which listed various observations related to the Pharmacy's sterile compounding operations.
3. On April 2, 2019, the Pharmacy initiated a voluntary recall of drug products intended to be sterile produced from September 24, 2018, to March 25, 2019. The recall was conducted out of an abundance of caution. There were no known adverse events associated with the recalled drug products.
4. The Pharmacy also informed the FDA that it had ceased all sterile compounding of human and veterinary products effective March 25, 2019, and that it did not intend to resume sterile compounding operations. The Pharmacy has not resumed sterile compounding operations since the FDA's inspection.
5. On January 13, 2020, the FDA issued a Warning Letter to the Pharmacy reciting the observations included in the Form FDA 483. The FDA instructed the Pharmacy to notify the FDA prior to resuming any sterile compounding operations.
6. The Pharmacy's Tennessee pharmacy permit, Facility License Number 2113, is currently active without any disciplinary action of record.
7. The Pharmacy has never sent or caused to be sent any compounded sterile products into the State of Maryland.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that a Pre-Charge Consent Order is appropriate and authorized under Md. Code Ann., Health Occ. § 12-403(g). This Pre-Charge Consent Order does not constitute discipline.

ORDER

Based upon an affirmative vote of the Board under the authority of Md. Code Ann., Health Occ. Art. § 12-409, it is this 4th day of June, 2021, hereby,

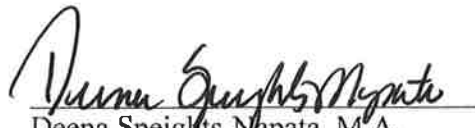
ORDERED that Anderson Compounding Pharmacy, Inc., Permit No. P06449, shall be prohibited from dispensing any sterile drug products into the State of Maryland, except for products dispensed in manufacturer's original packaging; and be it further,

ORDERED that Anderson Compounding Pharmacy, Inc., may resume dispensing sterile drug products into Maryland provided that the Pharmacy has: (1) submitted corrective actions in response to the FDA's Warning Letter, dated January 13, 2020; (2) demonstrated full compliance with USP 797 to the Board's satisfaction; and (3) given advanced written notice to the Maryland Board of its intent to resume dispensing sterile drugs products into Maryland; and be it further,

ORDERED that in the event that it resumes dispensing sterile drugs products into Maryland, Anderson Compounding Pharmacy shall comply with all laws and regulations governing the operation of a non-resident pharmacy in the State of Maryland, to include Maryland laws governing the compounding and dispensing of sterile drug products; and be it further,

ORDERED that this is a formal order and as such is a public document pursuant to Md. Code Ann., General Provisions Article § 4-301, *et seq.*

6-4-21
Date


Deena Speights-Napata, M.A.
Executive Director for:

~~Kevin Morgan, Pharm.D.~~ Jennifer Hardesty
Board President

CONSENT

1. By signing this Consent, Anderson Compounding Pharmacy, Inc., submits to the foregoing Consent Order as a resolution of this matter and agrees to be bound by its terms and conditions.


2. Anderson Compounding Pharmacy, Inc., acknowledges the validity of this Consent Order as if it were made after a hearing in which it would have had the right to counsel, to confront witnesses, and to all other substantial procedural protections provided by law.

3. Anderson Compounding Pharmacy, Inc., acknowledges that, by entering into this Consent Order, it is waiving its right to appeal any adverse ruling of the Board that might have followed such an evidentiary hearing.

4. Anderson Compounding Pharmacy, Inc., acknowledges the legal authority and the jurisdiction of the Board to enter and enforce this Consent Order.

5. Anderson Compounding Pharmacy, Inc., signs this Consent Order freely and voluntarily, after having had the opportunity to consult with counsel. Anderson Compounding Pharmacy, Inc., fully understands the language, meaning, and effect of this Consent Order.

4.21.2021
Date



Roy C. Anderson, R.Ph.
Owner

STATE OF Tennessee
COUNTY/CITY OF Sullivan:

I hereby certify that on this 21 day of April, 2021, before me, a Notary Public of the State of Tennessee and County/City aforesaid, personally appeared ROY C. ANDERSON, and made an oath in due form that the foregoing Consent was his voluntary act and deed on behalf of Anderson Compounding Pharmacy, Inc.



Susan L. Salyer
Notary Public
My commission expires: 11/23/24