

**IN THE MATTER OF** \* **BEFORE THE**  
**MEDITECH LABORATORIES, INC.** \* **MARYLAND STATE**  
**PERMIT NO. P04065** \* **BOARD OF PHARMACY**  
\* **Case No. PI-17-041**

\* \* \* \* \*

**CONSENT ORDER**

**Background**

In March 2016, the Maryland Board of Pharmacy (the “Board”) received notification from the Food and Drug Administration (“FDA”) that Meditech Laboratories, Inc., (the “Pharmacy”) was issued an FDA 483 with inspectional observations relating to the Pharmacy’s sterile compounding operations. The FDA subsequently issued a Warning letter on October 19, 2016. In response to the 483 observations and the Warning letter issued by the FDA, the Pharmacy indicated that it was ceasing all sterile compounding operations.

In lieu of instituting formal proceedings against Meditech Laboratories, Inc. in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 *et seq.*, the Board and Meditech Laboratories, Inc., have agreed to resolve this matter as set forth in this Consent Order.

**FINDINGS OF FACT**

1. Meditech Laboratories, Inc., is a pharmacy located in Las Vega, Nevada, holding non-resident permit number P04065.
2. In March 2016, the FDA conducted inspections of the Pharmacy’s sterile compounding operations. As a result, the FDA issued an FDA Form 483 list of observations that cited various USP 797 violations.

3. In April 2016, the Pharmacy initiated two recalls for several lots of drug products based on the FDA's observations. The recalls were completed in June 2016.
4. On October 19, 2016, the FDA issued a Warning letter to the Pharmacy based on the March FDA 483 observations.
5. On February 17, 2017, the Board received notice from the Pharmacy that it ceased its sterile compounding operations and did not intend to re-commence sterile compounding of any products.
6. The Pharmacy's Nevada pharmacy permit is currently active without any disciplinary action of record.

#### CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that Meditech Laboratories, Inc., Permit Number P04065, is subject to discipline in accordance with Md. Code Ann., Health Occ. § 12-403(g).

#### ORDER

Based upon an affirmative vote of the Board under the authority of Md. Code Ann., Health Occ. Art. § 12-409, it this 26<sup>th</sup> day of July, 2017, hereby,

ORDERED that Meditech Laboratories, Inc., Permit No. P04065, 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,

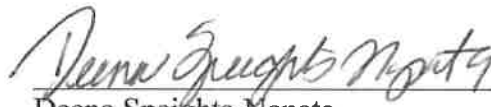
ORDERED that Meditech Laboratories, Inc., may resume dispensing sterile drugs products into Maryland provided that the Pharmacy has: (1) submitted corrective actions in response to the FDA's Warning letter, dated October 19, 2016; (2) demonstrated full compliance with USP 797 to the Board's satisfaction; 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 Meditech Laboratories, Inc., in the event that it resumes dispensing sterile drugs products into Maryland, 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 prescription drugs; 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 § 4-333.

7-26-17  
Date

  
Deena Speights-Napata,  
Executive Director for:

Mitra Gavvani, Pharm.D.  
Board President

**CONSENT**

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

2. Meditech Laboratories, 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. Meditech Laboratories, 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. Meditech Laboratories, Inc., acknowledges the legal authority and the jurisdiction of the Board to enter and enforce this Consent Order.

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

7/25/17  
Date

Michael Bitar  
Name: Michael Bitar  
Title: Pharmacist In Charge

STATE OF Nevada  
COUNTY/CITY OF Clark :

I hereby certify that on this 25 day of July, 2017, before me, a Notary Public of the State of Nevada and County/City aforesaid, personally appeared Michael Bitar, and made an oath in due form that the foregoing Consent was his/her voluntary act and deed on behalf of Meditech Laboratories, Inc.



[Signature]  
Notary Public  
My commission expires: Dec 28, 2019