

**IN THE MATTER OF
MEDAUS PHARMACY
PERMIT NO. P02645**

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**BEFORE THE
MARYLAND STATE
BOARD OF PHARMACY
Case No. PI-16-208**

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CONSENT ORDER

Background

The Maryland Board of Pharmacy (the “Board”) received notification from the National Association of Boards of Pharmacy (“NABP”) that Medaus, Inc., dba Medaus Pharmacy (the “Pharmacy”) was formally disciplined by the Alabama Board of Pharmacy based on violations of sterile compounding standards.

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

FINDINGS OF FACT

1. On or about September 19, 2001, the Pharmacy was issued a non-resident pharmacy permit to operate in Maryland under Permit Number P02645. The Pharmacy’s permit is active and will expire on May 31, 2018.
2. The Pharmacy dispenses a variety of sterile compounded products, to include products used for nutritional deficiencies, hormone replacement, metabolic disorders, environmental toxicities, and sexual dysfunction.
3. On or about March 7, 2016, the Food and Drug Administration (“FDA”) conducted an inspection of the Pharmacy. Based on such inspection, the FDA

issued a Form 483 list of observations relating to certain deficiencies in the Pharmacy's sterile compounding process.

4. On March 15, 2016, the Alabama Board of Pharmacy issued an emergency suspension of the Pharmacy's sterile compounding practice based on the FDA's Form 483 observations.
5. On May 6, 2016, the FDA issued a formal letter to the Pharmacy requesting a voluntary recall of all dispensed drug products intended to be sterile that were still within expiration.
6. On May 14, 2016, the Pharmacy issued a recall letter for the affected products.
7. On July 1, 2016, the Alabama Board of Pharmacy issued a Final Order in which it prohibited the Pharmacy from engaging in sterile compounding, excluding products dispensed in manufacturer's original packaging, for a minimum of two years from the effective date of the order. The Pharmacy was also assessed a fine of \$240,000.
8. On July 8, 2016, the Pharmacy notified the Board regarding the Alabama Board of Pharmacy action.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that Medaus Pharmacy, Permit Number P02645, 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 11th day of October, 2016, hereby,

ORDERED that Medaus Pharmacy, Permit No. P02645, shall be prohibited from dispensing any sterile drug products into the State of Maryland, except for products dispensed in manufacturer's original packaging, for a minimum of TWO (2) YEARS, effective July 1, 2016; and be it further,

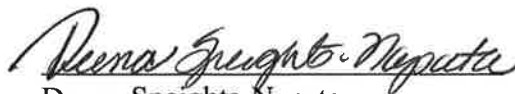
ORDERED that Medaus Pharmacy, may resume dispensing sterile drugs products into Maryland provided that the Pharmacy has: (1) fully satisfied the terms and conditions of the Alabama Board of Pharmacy Final Order, dated July 1, 2016; and (2) given written notice to the Maryland Board of its intent to resume dispensing sterile drugs products into Maryland; and be it further,

ORDERED that Medaus Pharmacy, upon resuming the 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 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.

Oct. 11, 2016

Date



Deena Speights-Napata,
Executive Director for:

Mitra Gavvani, Pharm.D.
Board President

CONSENT

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

2. Medaus Pharmacy 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. Medaus Pharmacy 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. Medaus Pharmacy acknowledges the legal authority and the jurisdiction of the Board to enter and enforce this Consent Order.

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

10/4/16
Date

Larry D. Stephens
Name: Larry D. Stephens
Title: C.O.O.

STATE OF Alabama
COUNTY/CITY OF Jefferson:

I hereby certify that on this 4th day of October, 2016, before me, a Notary Public of the State of Alabama and County/City aforesaid, personally appeared Larry D. Stephens, and made an oath in due form that the foregoing Consent was his/her voluntary act and deed on behalf of Medaus Pharmacy.



Notary Public
My commission expires: _____

**MY COMMISSION EXPIRES
DECEMBER 19, 2017**