

WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES



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STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY :
PROCEEDINGS AGAINST :
 : FINAL DECISION AND ORDER
MEDAUS PHARMACY, :
RESPONDENT. :

0005130

Division of Legal Services and Compliance Case No. 16 PHM 062

The parties to this action for the purpose of Wis. Stat. § 227.53 are:

Medaus Pharmacy
6801 Cahaba Valley Road, Suite 116
Birmingham, AL 35242

Wisconsin Pharmacy Examining Board
P.O. Box 8366
Madison, WI 53708-8366

Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190
Madison, WI 53707-7190

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final disposition of this matter, subject to the approval of the Pharmacy Examining Board (Board). The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. Respondent Medaus Pharmacy is licensed in the state of Wisconsin as an out-of-state pharmacy, having license number 346-43, first granted on June 6, 2008, and current through May 31, 2018. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is 6801 Cahaba Valley Road, Suite 116, Birmingham, AL 35242.

2. On April 1, 2016, the Federal Drug Administration (FDA) issued an FDA Alert – Lack of Sterility Assurance regarding Medaus Pharmacy. It stated:

- a. During FDA's recent inspection of Medaus' facility, investigators observed insanitary conditions, including poor sterile production practices, which raise concerns about Medaus' ability to assure the sterility of drug products that it produced. Administration of non-sterile product, intended to be sterile, may result in serious and potentially life-threatening infections or death. The Alabama Board of Pharmacy ordered Medaus to cease sterile compounding operations on March 22, 2016. On March 29, 2016, FDA recommended Medaus recall all unexpired drug products that are intended to be sterile. To date, Medaus has not voluntarily recalled any drug products intended to be sterile. Therefore, FDA alerts health care professionals and patients not to use drug products marketed as sterile from Medaus.

3. On July 1, 2016, the Alabama State Board of Pharmacy issued a Final Order concerning Respondent as follows:

- a. There is a finding of a violation by the Respondent of Code of Alabama (1975), § 34-23-33 (13) in that it violated Board Rule 688-X-2-.22 (2) (a) (d) and (f) based upon the Respondent's failure to comply with Section 503 (a) of the Federal Food, Drug and Cosmetic Act. As Amended, as it relates to sterility and endotoxin testing, assignment of beyond use dates and its failure to comply with environmental standards and quality control standards.
- b. The Respondent may not engage in sterile compounding or dispensing any sterile drug products, excluding those dispensed in manufacturer's original packaging, for a minimum of two years from the effective date of this Final Order, the date which it is signed on behalf of the Board.
- c. The Respondent shall pay the Board an administrative fine of Two Hundred and Forty Thousand (\$240,000.00) Dollars payable in thirty-six (36) equal monthly payments beginning on July 15, 2016 and thereafter on the fifteenth of the each following month until paid in full. After two years, and if the obligation is paid, the fine is satisfied, the Respondent may petition the Board to resume sterile compounding upon demonstrated compliance by the Respondent of applicable requirements. The Respondent may not so petition before two years from the effective date of this order.
- d. The Respondent may only dispense drugs on patient specific prescriptions, both domestic and international.
- e. All counts of the Statement of Charges as Amended (Counts One through Sixty-Nine) will be dismissed with prejudice up to the present date.
- f. The administrative fine shall not be subject to discharge in bankruptcy nor shall the Respondent attempt to discharge the same.

- g. The Respondent's supervising pharmacist and the Respondent's attorney acknowledged and agreed that they had the authority to accept the terms on behalf of the Respondent, they fully understood the terms, conditions and contents of the same and accepted the terms.

4. In resolution of this matter, Respondent consents to the entry of the following Conclusions of Law and Order.

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to Wis. Stat. § 450.10(1), and is authorized to enter into the attached Stipulation pursuant to Wis. Stat. § 227.44(5).

2. By the conduct described in the Findings of Fact, Respondent violated Wis. Admin. Code § Phar 10.03(17), by having a pharmacy license subject to disciplinary action by a licensing authority.

3. As a result of the above violation, Respondent is subject to discipline pursuant to Wis. Stat. § 450.10(1)(a)2.

ORDER

1. The attached Stipulation is accepted.

2. Respondent Medaus Pharmacy is REPRIMANDED.

3. Respondent shall follow all of the terms of the Alabama Final Order dated July 1, 2016.

4. Within one hundred and eighty (180) days from the date of this Order, Respondent Medaus Pharmacy shall pay a FORFEITURE of \$5000.00 and COSTS of this matter in the amount of \$215.00.

5. Payment of costs and forfeiture (made payable to the Wisconsin Department of Safety and Professional Services) shall be sent by Respondent to the Department Monitor at the address below:

Department Monitor
Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190, Madison, WI 53707-7190
Telephone (608) 267-3817; Fax (608) 266-2264
DSPSMonitoring@wisconsin.gov

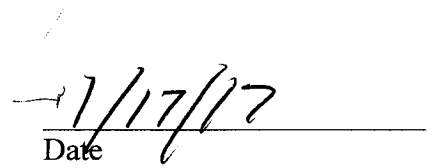
6. Violation of any of the terms of this Order may be construed as conduct imperiling public health, safety and welfare and may result in a summary suspension of Respondent's license. The Board in its discretion may in the alternative impose additional

conditions and limitations or other additional discipline for a violation of any of the terms of this Order. In the event Respondent fails to timely submit payment of costs or forfeiture as ordered, Respondent's license (no. 346-43) may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with payment of costs.

7. This Order is effective on the date of its signing.

WISCONSIN PHARMACY EXAMINING BOARD

by: 
A Member of the Board


Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY
PROCEEDINGS AGAINST

MEDAUS PHARMACY,
RESPONDENT.

:
:
:
:
:

STIPULATION

0005130

Division of Legal Services and Compliance Case No. 16 PHM 062

Respondent Medaus Pharmacy and the Division of Legal Services and Compliance, Department of Safety and Professional Services stipulate as follows:

1. This Stipulation is entered into as a result of a pending investigation by the Division of Legal Services and Compliance. Respondent consents to the resolution of this investigation by Stipulation.

2. Respondent understands that by signing this Stipulation, Respondent voluntarily and knowingly waives the following rights:

- the right to a hearing on the allegations against Respondent, at which time the State has the burden of proving those allegations by a preponderance of the evidence;
- the right to confront and cross-examine the witnesses against Respondent;
- the right to call witnesses on Respondent's behalf and to compel their attendance by subpoena;
- the right to testify on Respondent's own behalf;
- the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision;
- the right to petition for rehearing; and
- all other applicable rights afforded to Respondent under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and other provisions of state or federal law.

3. Respondent is aware of Respondent's right to seek legal representation and has been provided an opportunity to obtain legal counsel before signing this Stipulation. Respondent is represented by Attorney H. Hube Dodd.

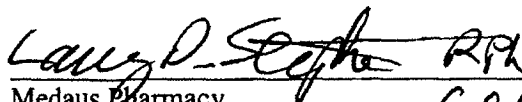
4. Respondent agrees to the adoption of the attached Final Decision and Order by the Wisconsin Pharmacy Examining Board (Board). The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall then be returned to the Division of Legal Services and Compliance for further proceedings. In the event that the Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.


6. The parties to this Stipulation agree that the attorney or other agent for the Division of Legal Services and Compliance and any member of the Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of Respondent or Respondent's attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with deliberations on the Stipulation. Additionally, any such advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's Final Decision and Order is a public record and will be published in accordance with standard Department procedure.


8. The Division of Legal Services and Compliance joins Respondent in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.


Medaus Pharmacy *C.O.O.*
6801 Cahaba Valley Road, Suite 116
Birmingham, AL 35242
License no. 346-43

11-11-16
Date


H. Hube Dodd, Attorney for Respondent
The Dodd Law Firm
2323 Second Avenue North
Birmingham, AL 35242

11/11/16
Date


Cody Wagner, Attorney
Department of Safety and Professional Services
Division of Legal Services and Compliance
P.O. Box 7190
Madison, WI 53707-7190

11/11/16
Date