

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
CUSTOM MEDS, INC., :
RESPONDENT. :

0004632

Division of Legal Services and Compliance Case No. 15 PHM 069

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

Custom Meds, Inc.
102 East Highland Boulevard
Inverness, FL 34452

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 Custom Meds, Inc., is licensed in the state of Wisconsin to practice as an out-of-state pharmacy, having license number 791-43, first issued on July 9, 2012 and current through May 31, 2016. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is 102 East Highland Boulevard, Inverness, FL 34452.

2. On May 6, 2015, the Wisconsin Board of Pharmacy was notified by Custom Meds, Inc., that their pharmacy and pharmacist received professional discipline in the state of Florida by virtue of *State of Florida, Board of Pharmacy, Department of Health v. Custom Meds, Inc., Case No. 2013-18732* and *State of Florida, Board of Pharmacy, Department of Health v.*

Jessica Ellen Dileo, Case No. 2014-09491 (Florida Orders). Each Respondent was ordered to pay an administrative fine of \$2,000.00.

3. On or about October 12, 2012, Dr. S.G., D.O. wrote a prescription for patient R.F., who was a patient and customer of Custom Meds, Inc., for a three month supply of 360 capsules of domperidone 10mg.

4. Domperidone is an antiemetic drug that reduces nausea and vomiting, and speeds the transit of food through the stomach. Domperidone is not a drug approved by the Food and Drug Administration (FDA) and is not an active ingredient contained in any FDA approved drug.

5. The FDA Expanded Access to Investigational Drugs program permits patients with certain gastrointestinal conditions to be treated with domperidone if the prescribing physician submits an investigational new drug application (IND) to the FDA.

6. On or about October 17, 2012, Custom Meds, Inc., dispensed 360 capsules of domperidone 10mg to patient R.F.

7. Custom Meds, Inc., introduced domperidone, a new drug, into interstate commerce without the FDA's approval of an IND application for domperidone by dispensing domperidone to patient R.F. on or about October 17, 2012.

8. 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, Custom Meds, Inc., violated Wis. Admin Code § Phar 10.03(17) by having a pharmacist license revoked or suspended in another state or United States jurisdiction or having been subject to other disciplinary action by the licensing authority thereof.

3. By the conduct described in the Findings of Fact, Custom Meds, Inc., violated Wis. Stat. § 450.10(1)(a)6, by engaging in conduct in the practice of the licensee which evidences a lack of knowledge or ability to apply professional principles or skills..

4. As a result of the above violations, Custom Meds, Inc., is subject to discipline pursuant to Wis. Stat. § 450.10(1)(b).

ORDER

1. The attached Stipulation is accepted.
2. Respondent Custom Meds, Inc., is REPRIMANDED.

3. Respondent Custom Meds, Inc., shall comply with the requirements set forth in the Final Order Approving Counter Settlement Agreement and the Settlement Agreement. *State of Florida, Board of Pharmacy, Department of Health v. Custom Meds, Inc., Case No. 2013-18732.*

4. Within ninety (90) days from the date of this Order, Custom Meds, Inc., shall pay COSTS of this matter in the amount of \$150.00.

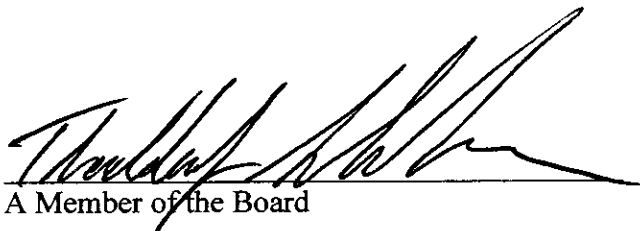
5. Payment of costs (made payable to the Wisconsin Department of Safety and Professional Services) shall be sent by Respondent to the Department Monitor at the address below:

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 as ordered or violates the Florida Order, Respondent's license (no. 791-43) 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

4/7/16
Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY	:	
PROCEEDINGS AGAINST	:	
	:	STIPULATION
CUSTOM MEDS, INC.,	:	
RESPONDENT.	:	0004632

Division of Legal Services and Compliance Case No. 15 PHM 069

Respondent Custom Meds, Inc., 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.

4. Respondent agrees to the adoption of the attached Final Decision and Order by the Wisconsin Pharmacy Examining (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, 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.

J. Diheo
Custom Meds, Inc., Respondent
102 East Highland Boulevard
Inverness, FL 34452
License No. 791-43

3-7-2016
Date

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

March 8 2016
Date