

WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES



Wisconsin Department of Safety and Professional Services Access to the Public Records of the Reports of Decisions

This Reports of Decisions document was retrieved from the Wisconsin Department of Safety and Professional Services website. These records are open to public view under Wisconsin's Open Records law, sections 19.31-19.39 Wisconsin Statutes.

Please read this agreement prior to viewing the Decision:

- The Reports of Decisions is designed to contain copies of all orders issued by credentialing authorities within the Department of Safety and Professional Services from November, 1998 to the present. In addition, many but not all orders for the time period between 1977 and November, 1998 are posted. Not all orders issued by a credentialing authority constitute a formal disciplinary action.
- Reports of Decisions contains information as it exists at a specific point in time in the Department of Safety and Professional Services data base. Because this data base changes constantly, the Department is not responsible for subsequent entries that update, correct or delete data. The Department is not responsible for notifying prior requesters of updates, modifications, corrections or deletions. All users have the responsibility to determine whether information obtained from this site is still accurate, current and complete.
- There may be discrepancies between the online copies and the original document. Original documents should be consulted as the definitive representation of the order's content. Copies of original orders may be obtained by mailing requests to the Department of Safety and Professional Services, PO Box 8935, Madison, WI 53708-8935. The Department charges copying fees. *All requests must cite the case number, the date of the order, and respondent's name* as it appears on the order.
- Reported decisions may have an appeal pending, and discipline may be stayed during the appeal. Information about the current status of a credential issued by the Department of Safety and Professional Services is shown on the Department's Web Site under "License Lookup."

The status of an appeal may be found on court access websites at:

<http://ccap.courts.state.wi.us/InternetCourtAccess> and <http://www.courts.state.wi.us/wscga>

- Records not open to public inspection by statute are not contained on this website.

By viewing this document, you have read the above and agree to the use of the Reports of Decisions subject to the above terms, and that you understand the limitations of this on-line database.

Correcting information on the DSPS website: An individual who believes that information on the website is inaccurate may contact DSPS@wisconsin.gov

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF THE DISCIPLINARY :
PROCEEDINGS AGAINST :
 : FINAL DECISION AND ORDER
DOWNING LABS, LLC, :
RESPONDENT. :

0004462

Division of Legal Services and Compliance Case No. 15 PHM 170

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

Downing Labs, LLC
4001 McEwen Road
Suite 110 & 120
Dallas, Texas 75244

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

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

PROCEDURAL HISTORY

The parties have agreed to the terms and conditions of the attached Stipulation and Interim Order in 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 adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law and Order:

FINDINGS OF FACT

1. Respondent Downing Labs, LLC, is licensed in the state of Wisconsin as an out-of-state pharmacy, having license number 1305-43, first issued on August 29, 2014 and current through May 31, 2016. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services is 4001 McEwen Road, Suite 110 & 120, Dallas, Texas 75244.

2. On June 25, 2014, the State of Texas licensed Respondent as a pharmacy. The 2014 license was the result of a change in ownership. Under its previous owners, Respondent operated as NuVision Pharmacy, Inc. (NuVision).

3. On July 31, 2014, the Michigan Board of Pharmacy summarily suspended NuVision's license to practice as an out-of-state pharmacy and also suspended NuVision's license to dispense controlled substances (the Michigan action). The suspension was based on NuVision's failure to initiate a recall of products that were to have been compounded under sterile conditions.

4. The FDA's request for a recall was based on an inspection and testing performed on product lots produced by NuVision between March 18, 2013 and April 16, 2013, before Respondent was licensed in Wisconsin. The FDA concluded that the products were compounded under conditions that compromised their sterility.

5. On February 2, 2015, the Virginia Board of Pharmacy issued an Order of Mandatory Suspension (the Virginia action), which immediately suspended Respondent's Virginia non-resident pharmacy registration. The Virginia action against Respondent was based on the Michigan action against NuVision.

6. While attempting to resolve the discrepancy between parties in the MI action against NuVision and VA action against Respondent, Respondent did not report the Virginia action to the Wisconsin Pharmacy Examining Board.

7. On October 21, 2015, Respondent recalled its sterile compounded products due to a lack of sterility assurance. Respondent has since ceased all sterile compounding.

8. As of December 18, 2015, at the Division's request, Respondent has voluntarily refrained from doing any business in the state of Wisconsin.

9. Respondent denies intentional wrong-doing, but consents to entry of the Conclusions of Law and Order set out below.

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction over 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. Respondent, by having its license suspended in another state, has engaged in unprofessional conduct as defined by Wis. Admin. Code § Phar 10.03.

3. Respondent, by failing to report the out-of-state actions to the Wisconsin Pharmacy Examining Board has engaged in unprofessional conduct as defined by Wis. Admin. Code § Phar 10.03(7).

4. Respondent is therefore subject to discipline pursuant to Wis. Stat. § 450.10(1)(b), and is subject to a forfeiture pursuant to Wis. Stat. § 450.10(2).

ORDER

1. The license to practice as an out-of-state pharmacy in the state of Wisconsin of Respondent Downing Labs, LLC, license number 1305-43, is hereby **SUSPENDED** for a period of sixty days, retroactive to December 18, 2015.

2. The license to practice as an out-of-state pharmacy in the state of Wisconsin of Respondent Downing Labs, LLC, license number 1305-43, is **LIMITED** in that Respondent shall not sell, or otherwise cause to be shipped into the state of Wisconsin, products which are required to be compounded under sterile conditions. This limitation shall be removed when Respondent submits proof, satisfactory to the Board or its designee, that Respondent has undergone a favorable inspection by the National Associations of Boards of Pharmacy or other qualified entity as determined by the Board or its designee.

3. Within 90 days of the date of this Order, Respondent shall pay a **FORFEITURE** of \$5,000.00.

4. Within 90 days of the date of this Order, Respondent shall pay **COSTS** of this matter in the amount of \$771.00.

5. Petitions to the Board, evidence in support of a petition and 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, failed to pay the forfeiture as ordered, or violates the prohibition on sterile compounding, Respondent's license (no. 1305-43) 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, payment of forfeiture or as the Board deems otherwise reasonable.

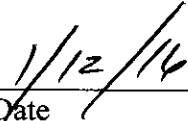
7. This Order is intended to address all out-of-state disciplinary matters arising from the Michigan action, the Virginia action and a pending Iowa matter (Iowa Board of Pharmacy Case no. 2015-48).

8. Except as specified in paragraph one of this Order, 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

:
:
:
:
:

STIPULATION

DOWNING LABS, LLC,
RESPONDENT.

0004462

Division of Legal Services and Compliance Case No. 15 PHM 170

Respondent Downing Labs, LLC, 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 an investigation by the Division of Legal Services and Compliance. Respondent consents to this final resolution.

2. Respondent understands that by signing this Stipulation, Respondent voluntarily and knowingly waives the following rights as they pertain to the attached final decision and order:

- 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 Melissa Gilmore.

4. Respondent neither admits nor denies the allegations in this matter, but agrees to the adoption of the attached final decision and order by the 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 be returned to the Division of Legal Services and Compliance for further proceedings. In the event that this 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 a case advisor in this investigation may appear before the Board in open or closed session, without the presence of Respondent or Respondent's attorney, if any, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with the Board's deliberations on the Stipulation. Additionally, any such case 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 that the Board adopt this Stipulation and issue the attached final decision and order.



Downing Labs, LLC, Respondent

ASHLEY DOWNING, Authorized Representative

4001 McEwen Road
Suite 110 & 120
Dallas, Texas 75244
License No. 1305-43

Date

1/4/2016



Sandra L. Nowack, Attorney

State Bar Number 1025643

Department of Safety and Professional Services

Division of Legal Services and Compliance

P.O. Box 7190

Madison, WI 53707-7190

Tel. (608) 266-8098

sandra.nowack@wisconsin.gov

Date

1/4/16