

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/wscca>

- 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 DISCIPLINARY :
PROCEEDINGS AGAINST :
 : FINAL DECISION AND ORDER
CALIFORNIA PHARMACY AND :
COMPOUNDING CENTER, :
RESPONDENT. : **0005481**

Division of Legal Services and Compliance Case No. 16 PHM 140

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

California Pharmacy and Compounding Center
4000 Birch St., #120
Newport Beach, CA 92660

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 California Pharmacy and Compounding Center is licensed in the state of Wisconsin as an out-of-state pharmacy, having license number 501-43, first issued on October 27, 2009, and current through May 31, 2018. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is 4000 Birch Street #120, Newport Beach, California 92660.

2. On May 25, 2016, Respondent and the Board of Pharmacy, Department of Consumer Affairs State of California (California Board) entered into a Stipulated Settlement and

Disciplinary Order in which Respondent's pharmacy license was placed on probation for four (4) years.

3. The Stipulated Settlement and Disciplinary Order was based on the following facts:

- a. Respondent failed to ensure the security, integrity and/or authority of a patient's prescription by failing to verify the prescription with the prescribing physician.
- b. Respondent compounded and dispensed prescriptions for Releana® containing significant errors, omissions, irregularities and/or uncertainties.
 - i. The Releana® prescriptions did not specify the quantity to dispense, directions for use or the date the prescription was issued.
 - ii. Electronically transmitted prescriptions for Releana® were not valid in that the prescriptions were received by Respondent from another entity other than the prescriber, and they were not verified with the prescribing physician.
 - iii. Electronically transmitted prescriptions for Releana® that were produced in hard-copy did not bear the date the prescription was transcribed, nor the signature of the transcribing pharmacist.
 - iv. Electronically transmitted prescriptions for Releana® did not identify the person who transmitted the prescriptions.
- c. Respondent compounded and sold Releana® to an entity that was not licensed as a pharmacy or wholesaler by the California Board.
- d. Respondent sold, delivered, transferred, held or offered for sale a drug that Respondent knew or should have known were misbranded.
 - i. The Releana® drugs were misbranded in that the label affixed to each individual container of Releana® powder and Releana® vehicle did not specify the name and address of the manufacturer, packager or distributor and did not specify the quantity of the contents of each of the two containers sold in terms of weight or measure.
- e. Respondent dispensed Releana® with prescription labels that did not state the concentration or strength of the active ingredient nor the quantity of the drug dispensed, either in volume, weight or numerical count.

- f. Respondent aided and abetted the violation of California law by selling Releana® to an entity not licensed as a pharmacy or wholesaler in the state of California who then sold Releana® to physicians in California and other states.
- g. Respondent failed to maintain a written policy and procedure manual that included the procedures for maintaining, storing, calibrating, cleaning, and disinfecting the autoclave and convection oven.
- h. Respondent assigned an erroneous expiration date to a prescription for sodium carboxymethylcellulose that exceeded the shortest expiration date of any component in the compounded drug product.
- i. Respondent failed to report an adverse event regarding a patient to the California Board within twelve (12) hours.
- j. Respondent assigned erroneous expiration dates to compounded oxytocin.
 - i. Between April 1, 2012 and September 1, 2015, Respondent compounded oxytocin 120/u/ml and 360/u/ml and assigned a beyond use date (BUD) of one (1) year without adequate supporting stability studies to justify the extended BUD.
- k. Respondent failed to complete and document end product testing of 49 batches of Trimix® for sterility and pyrogens and failed to quarantine until the end product testing confirmed sterility and acceptable levels of pyrogens.

4. As of February 14, 2017, Respondent is in compliance with the rules and regulations of the California Board.

5. 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, California Pharmacy and Compounding Center engaged in unprofessional conduct as defined by Wis. Admin. Code § Phar 10.03(17), by having a pharmacy 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. As a result of the above violations, California Pharmacy and Compounding Center is subject to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

1. The attached Stipulation is accepted.
2. Respondent California Pharmacy and Compounding Center is REPRIMANDED.
3. Within ninety (90) days from the date of this Order, California Pharmacy and Compounding Center shall pay FORFEITURE in the amount of \$500.00.
4. Within ninety (90) days from the date of this Order, California Pharmacy and Compounding Center shall pay COSTS of this matter in the amount of \$671.00.
5. Payment of forfeiture and 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:

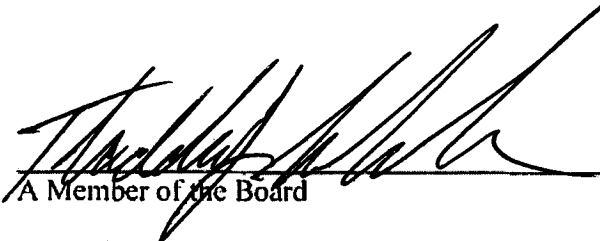
Department Monitor
Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190, Madison, WI 53707-7190
Telephone (608) 267-3817; Fax (608) 266-2264
DSPSMonitoring@wisconsin.gov

6. In the event that Respondent violates any term of this Order, Respondent's license (no. 501-43) to practice as an out-of-state pharmacy in the state of Wisconsin may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of the Order. The Board may, in addition and/or in the alternative refer any violation of this Order to the Division of Legal Services and Compliance for further investigation and action.

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

WISCONSIN PHARMACY EXAMINING BOARD

by:


A Member of the Board

10/26/17
Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY
PROCEEDINGS AGAINST

CALIFORNIA PHARMACY AND
COMPOUNDING CENTER,
RESPONDENT.

:
:
:
:
:
:
:

STIPULATION

0005481

Division of Legal Services and Compliance Case No. 16 PHM 140

Respondent California Pharmacy and Compounding Center 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.

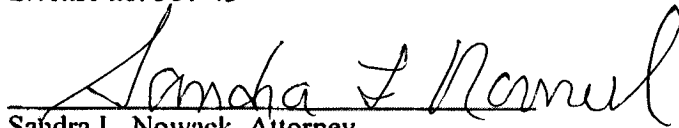
7. Respondent is informed that should the Board adopt this Stipulation, the Board's Final Decision and Order is a public record and will be published in accordance with standard Department procedure.

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.



California Pharmacy and Compounding Center, Respondent
4000 Birch St., #120
Newport Beach, CA 92660
License no. 501-43

09/12/17
Date



Sandra L. Nowack, Attorney
State Bar No. 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
Fax (608) 266-2264
sandra.nowack@wisconsin.gov

9/14/17
Date