

IN THE MATTER OF * BEFORE THE
LUPIN PHARMACEUTICALS, INC. * STATE BOARD OF
RESPONDENT-CORPORATION * PHARMACY
PERMIT NUMBER: D01631 * CASE NO.: PI-10-022

* * * * *

FINAL CONSENT ORDER

The State Board of Pharmacy (“the Board”) charged Lupin Pharmaceuticals, Inc., permit number: D01631 (the “Respondent-Corporation”), with violating certain provisions of the Maryland Pharmacy Act, (“the Act”) Md. Health Occ. Code Ann., (“H.O.”) §§12-101 *et seq.* (2014 Repl. Vol.). The pertinent provisions state:

H.O. § 12-601. Disciplinary actions.

(a) *In general* - Subject to the hearing provisions of § 12–315 of this title, for a violation of this subtitle, Subtitle 6C of this title, or any regulation adopted under Subtitle 6C of this title, the Board may:

- (1) Deny a permit to an applicant;
- (2) Reprimand a permit holder;
- (3) Place a permit holder on probation; or
- (4) Suspend or revoke a permit.

H.O. §12–6C–03. Permit required.

(a) A wholesale distributor shall hold a permit issued by the Board before the wholesale distributor engages in wholesale distribution in the State.

H.O. § 12-6C-11. Violations; penalties.

(a) *Fine.* – (1) If a person knowingly violates any provisions of this subtitle or any regulation adopted under this subtitle, the Board may impose a fine not to exceed \$500,000.

**Code Md. Regs. Tit. 10 § 34.22:
.05 Violations and Penalties.**

A. After a hearing held under Health Occupations Article, §12-601, Annotated Code of Maryland, the Board may deny, suspend, revoke, or place on probation a permit holder, reprimand a permit holder, or impose a fine if the permit holder:

(3) Commits any of the following acts:

(d) Violates a provision of, or regulation promulgated under, Health Occupations Article, Title 12, Annotated Code of Maryland;

(k) Sells or transfers a prescription drug or device to a person who is not legally authorized to receive a prescription drug or device;

(n) Fails to obtain a license, or operates without a valid license when a license is required;

(v) Otherwise conducts the wholesale distribution of prescription drugs or devices in a manner not in accordance with the law [.]

FINDINGS OF FACT

The Board finds that:

1. The Respondent-Corporation was originally issued a permit to operate as a wholesale distributor on or about March 23, 2004. The Respondent-Corporation's current permit expires on May 31, 2015.

2. The Respondent-Corporation is a manufacturer of drugs and medical devices and its corporate headquarters is located at III South Calvert Street, Baltimore, Maryland. The Respondent-Corporation does not manufacture or take possession of any pharmaceutical products at its Maryland location. Respondent-Corporation ships product into Maryland utilizing a licensed third-party logistics provider, located outside the State of Maryland.

3. In or around January 2014, investigation by the Board's staff revealed that Respondent-Corporation's permit lapsed from January 2009 to December 2009. Between January 2009 and December 2009, Respondent-Corporation, through a properly licensed third-party logistics provider, shipped approximately \$6.9 million dollars of prescription drugs and/or devices to four wholesale distributors located in Maryland.

4. During the period that these transactions occurred, the Respondent-Corporation did not hold a current and valid wholesale distributor permit issued by the Board.

5. The Respondent-Corporation wholesale distributor permit lapsed and was not renewed for 2009 because of a misunderstanding by Respondent-Corporation that a license for its Maryland corporate headquarters was not necessary. In February 2010, Respondent-Corporation promptly renewed its license and paid a reinstatement fee after communication with Board staff that it was required to maintain a wholesale distributor permit at its Baltimore location.

6. The Board has inspected Respondent-Corporation at least three times since 2010 without notice of any violations.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Respondent violated H.O. § 12-6C-03; H.O. § 12-6C-11, and (3); Code Md. Regs. tit. 10 § 34.22.05.A (3) (d), (k), (n), and (v).

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is this 18th day of February 2015, by a majority of the quorum of the Board, hereby

ORDERED that the Respondent-Corporation shall pay a fine in the amount of thirty thousand dollars (\$30,000). The fine is payable to the Maryland Board of Pharmacy no later than 90 (ninety) days from the date that this Order is signed by the Board; and it is further

ORDERED that the Respondent-Corporation shall not distribute prescription drugs in Maryland without a wholesale distributor permit; and it is further


ORDERED that Respondent shall be responsible for all costs incurred under this Order; and it is further

ORDERED that the effective date of this Order is the date that it is signed by the Board; and it is further

ORDERED that for purposes of public disclosure and as permitted by Md. General Provisions §§ 4-101 *et seq.* (2014), this document consists of the contents of the foregoing Findings of Fact, Conclusions of Law, and Order, and is reportable to any entity to whom the Board is obligated to report; and it is further

ORDERED that this Order is final and a public document pursuant to Md. General Provisions §§ 4-104 *et seq.* (2014).

Date 2/18/2015



Lenna Israbian-Jamgochian, P.D.
President
State Board of Pharmacy

**CONSENT OF LUPIN PHARMACEUTICALS, INC., BY SEAN MORIARTY, VICE
PRESIDENT, LEGAL AFFAIRS**

I, Sean Moriarty, by affixing my signature hereto, acknowledge that:

1. Lupin Pharmaceuticals, Inc. ("Lupin") is represented by Douglas B. Farquhar and John A. Gilbert, Jr.

2. I, as Vice President of Legal Affairs for Lupin, am aware that Lupin is entitled to a formal evidentiary hearing before the Board, pursuant to Md. Health Occ. Code Ann. § 12-315 (Repl. Vol. 2014) and Md. State Govt. Code Ann. §§ 10-201 *et seq.* (Repl. Vol. 2014).

3. I, as Vice President of Legal Affairs for Lupin, acknowledge the validity and enforceability of this Consent Order as if entered after a formal evidentiary hearing in which Lupin would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on its own behalf, and to all other substantive and procedural protections provided by law. Lupin is waiving those procedural and substantive protections.

4. I, as Vice President of Legal Affairs for Lupin, voluntarily, on behalf of Lupin, enter into and consent to the foregoing findings of fact, conclusions of law, and order and certify that Lupin agrees to abide by the terms and conditions set forth in this Consent Order, as a resolution of the Board's case, based on the findings set forth herein. Lupin does not admit to any knowing violations of law, but, in the interests of avoiding unnecessary time and expense associated with a contested hearing, agrees to execute this Final Consent Order.

5. Lupin waives its right to contest the findings of fact and conclusions of law, and waives its right to a full evidentiary hearing, and any right to appeal this Consent Order

as set forth in Md. Health Occ. Code Ann. § 4-319 (Rep. Vol. 2014) and Md. State Govt. Code Ann. §§ 10-201 *et seq.* (Rep. Vol. 2014).

6. I, as Vice President of Legal Affairs for Lupin, acknowledge that by failing to abide by the terms and conditions set forth in this Consent Order, and, following proper procedures, Lupin may be subject to disciplinary action.

7. I, as Vice President of Legal Affairs for Lupin, sign this consent order, without reservation, as my voluntary act and deed. I, as Vice President of Legal Affairs for Lupin, acknowledge that Lupin fully understands and comprehends the language, meaning, and terms of this Consent Order.

9 FEB 2015

Date

A handwritten signature in blue ink, appearing to read "Sean Moriarty", written over a horizontal line.

Sean Moriarty
Vice President, Legal Affairs

NOTARY

STATE OF Maryland
CITY/COUNTY OF Baltimore City

I hereby certify that on this 9 day of February, 2015, before me, a Notary Public, personally appeared Sean Moriarty, Vice President, Legal Affairs, Lupin Pharmaceuticals, Inc., made oath in due form of law that signing the foregoing Consent Order was a voluntary act and deed.

AS WITNESS my hand and Notarial Seal.



Notary Public



My Commission Expires: