

On March 20, 2013, the Maryland State Board of Pharmacy (the "Board") charged **VORTECH PHARMACEUTICALS, LTD. (the "Respondent-Distributor") (Unlicensed)**, under the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. ("H.O.") §§ 12-101 *et seq.* (2009 Repl. Vol. and 2010 Supp.).

The pertinent provisions of the Act provide as follows:

H.O. § 12-6C-03. Permit Required.

(a) Wholesale distributor. – 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.

On May 22, 2013, the Respondent-Distributors appeared before members of the Board and the Board's counsel for a Case Resolution Conference (CRC) to discuss the potential resolution of the Charges by consent. At the conclusion of the CRC, the Respondent-Distributor agreed to enter into this Consent Order to resolve the pending charges and to avoid the expense and time of proceeding to an administrative hearing. The Respondent-Distributor and the Board agreed to the inclusion of Findings of Fact and Conclusions of Law as required by the Board, and with the terms and conditions set forth

herein.

FINDINGS OF FACT

The Board finds the following:

- 1. The Respondent-Distributor is located in Dearborn, Michigan and is a manufacturer regulated by the Food and Drug Administration.
- 2. At the time of the allegations, the Respondent-Distributor did not hold and had never held a Maryland distributor permit. On or about December 5, 2012, the Maryland Division of Drug Control ("DDC") was conducting an opening inspection at Queen Anne County Animal Control Center in Queenstown, Maryland when the DDC inspector observed one invoice for Fatal Plus¹ from the Respondent-Distributor.
- 3. The DDC inspector notified the Board after it could not ascertain whether the Respondent-Distributor held a distributor permit in Maryland.
 - 4. Thereafter, the Board initiated an investigation.
- 5. The Board's investigator determined that the Respondent-Distributor did not hold a distributor permit and an application was not pending.
- 6. On or about December 13, 2012, the Board issued a subpoena for copies of invoices for all prescription medications that the Respondent-Distributor shipped to the State of Maryland.
- 7. On or about December 19, 2013, the Respondent-Distributor provided invoices for product shipped to Maryland in 2012.

¹ Fatal Plus contains pentobarbital sodium as the active ingredient and is used to euthanize animals. It is a schedule II controlled dangerous substance.

- 8. According to the invoices, the Respondent-Distributor distributed approximately in \$40,000 worth of Fatal-Plus in Maryland in 2012.
- 9. In a letter accompanying the invoices, the Respondent-Distributor stated that while it primarily sells through distributors, it also sells directly to humane societies and city shelters to help keep costs low for these organizations.
- 10. Although many of the invoices were for humane societies and city shelters, the Respondent-Distributor also sold Fatal-Plus to other veterinary establishments. The Respondent estimates that approximately 80% of the sales in Maryland were to humane societies and city shelters, while the remaining 20% were to private veterinary practices.
- 11. On May 3, 2013, the Board issued the Respondent-Distributor a wholesale distributor permit (D05241).
- 12. The Respondent-Distributor's actions as outlined in pertinent part above constitute a violation of H.O. § 12-6C-03(a).

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent-Distributor violated the following provision of the Act: H.O. § 12-6C-03(a).

<u>ORDER</u>

Based on agreement of the parties, it is therefore this _____day of June 2013, by an affirmative vote of the Board, hereby:

ORDERED that within 90 days of the effective date of this Consent Order, the Respondent-Distributor shall pay a fine in the amount of **\$1,500**, payable to the Maryland Board of Pharmacy; and it is further

ORDERED that failure to comply with the terms and conditions of this Consent

Order, including but not limited to failure to pay the required fine, constitutes a violation of

this Consent Order and the Board, in its discretion, after notice and an opportunity for a

show cause hearing before the Board may impose any appropriate sanction under the Act;

and it is further

ORDERED the Respondent-Distributor shall bear all expenses associated with this

Order; and it is further

ORDERED the Respondent-Distributor shall operate according to the Maryland

Pharmacy Act and in accordance with all applicable laws, statutes and regulations

pertaining to its operation as wholesale distributor; and it is further

ORDERED that this document constitutes a formal disciplinary action of the State

Board of Pharmacy and is therefore a public document for purposes of public disclosure,

pursuant to the Public Information Act, State Gov't § 10-611 et seq. and COMAR

10.34.01.12.

Michael N. Souranis, President

State Board of Pharmacy

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CONSENT

I, John A. MacNeil, President of Vortech Pharmaceuticals, Ltd. ("Vortech"), for and

on behalf of Vortech acknowledge that Vortech has had the opportunity to consult with

legal counsel before signing this document. By this Consent, Vortech agrees to be bound

by this Consent Order and its conditions and restrictions. Vortech waives any rights it may

have had to contest the Findings of Fact and Conclusions of Law.

Vortech acknowledges the validity of this Consent Order as if entered into after the

conclusion of a formal evidentiary hearing in which Vortech 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 as provided by law. Vortech

acknowledges the legal authority and the jurisdiction of the Board to initiate these

proceedings and to issue and enforce this Consent Order. Vortech waives any right to

appeal any adverse ruling of the Board that might have followed any such hearing.

I sign this Consent Order on behalf of Vortech without reservation, and I fully understand

and comprehend the language, meaning and terms of this Consent Order. I voluntarily

sign this Order, and understand its meaning and effect.

I am a duly authorized representative of Vortech and am legally authorized to sign

this consent order on behalf of Vortech.

6/11/2013 Date

John A. MacNeil, President

Vortech Pharmaceuticals, Ltd.

NOTARY

STATE OF MICHIGAN
CITY/COUNTY OF Living ston:
I HEREBY CERTIFY that on this // day of Jane, 2013, before
me, a Notary Public of the foregoing State personally appeared John A. MacNeil, President
of Vortech Pharmaceuticals, Ltd., and made oath in due form of law that signing the
foregoing Consent Order was his voluntary act and deed, and the statements made herein
are true and correct.
AS WITNESSETH my hand and notarial seal.
Blain E. Llanding Notary Public
My Commission Expires:
BLAIR E. HARDING Notary Public, State of Michigan County of Livingston My Commission Expires Nov 15, 2014 Acting in the County of Living Store