

IN THE MATTER OF	*	BEFORE THE
GULF COAST PHARMACEUTICALS, INC.	*	STATE BOARD OF
RESPONDENT	*	PHARMACY
PERMIT NUMBER: D02176	*	CASE NO.: PI 10-034

* * * * *

FINAL ORDER OF REVOCATION

The State Board of Pharmacy ("the Board") notified Gulf Coast Pharmaceuticals Inc., permit number: D02176 (the "Respondent"), of the Board's intent to revoke the wholesale distributor permit of Gulf Coast Pharmaceuticals Inc., under the Maryland Pharmacy Act, ("the Act") Md. Health Occ. Code Ann., ("H. O.") § 12-601. (Repl. Vol. 2009 & Supp. 2010).

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.

The pertinent provisions of state:

H.O. § 12-6C-09.

(b) A wholesale distributor may supply prescription drugs only to a person authorized by law to dispense or receive prescription drugs.

Code Md. Regs. tit. 10, § 34.22:

.04 Personnel.

B. Registered Agent.

(1) Each licensed wholesale distributor located outside of this State that wholesale distributes prescription drugs or devices in this State shall designate a registered agent in this State for service of process.

.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:

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

(4) Is disciplined by a licensing or disciplinary authority of any state or country, or disciplined by a court of any state or country, for an act that would constitute a ground for Board action against a wholesale distributor permit holder under §A or B of this regulation.

.07 Minimum Requirements for Maintenance of Prescription Drug or Device Distribution Records.

B. Written Policies and Procedures.

(1) A wholesale distributor shall establish, maintain, and adhere to written policies and procedures which shall be followed for:

(a) The receipt, security, storage, inventory, and distribution of prescription drugs or devices [.]

FINDINGS OF FACT

The Board finds that:

1. At all times relevant herein, the Respondent was originally issued a permit to operate as a wholesale distributor on or about June 12, 2007. The Respondent's permit expired on December 31, 2010.

2. The Respondent is located at 995 North Halstead Road, Ocean Springs, Mississippi.

3. The Respondent holds non-resident wholesale distributor permits in numerous states, including the State of Oklahoma.

4. The Respondent does not have a resident agent in the State of Maryland.

5. On or about April 30, 2010, the Board was notified by the National Association of Boards of Pharmacy that it had disqualified the Respondent from participating in the Verified-Accredited Wholesale Distributor (VAWD) program¹

6. VAWD disqualified the Respondent from participating in the VAWD program, because the Respondent's wholesale distributors license had been revoked by the State of Oklahoma Board of Pharmacy.

7. On or about January 15, 2010, the Respondent and the State of Oklahoma Board of Pharmacy ("Oklahoma Board") entered into a Consent Order. The Respondent agreed to pay a fine in the amount of \$22,500.00 (a copy of the Agreed Findings of Fact, Conclusions of Law and Final Order is attached hereto and incorporated herein as **Exhibit A**).

8. Under the terms of the Consent Order, the Respondent's non-resident

¹ VAWD is an accreditation program for wholesale distributors. VAWD is recognized and used by the Board. The Board granted the Respondent a wholesale drug distributor permit, based on the Respondent's VAWD accreditation, pursuant to § 12-6C-04 of the Act.

wholesale permit was revoked by the Oklahoma Board.

9. The Oklahoma Board revoked the Respondent's non-resident wholesale permit for failure to report to the Oklahoma Board shipments of large quantities of drugs to two pharmacies between December 2008 and July 2009.

10. Between December 2008 and June 2009, the Respondent shipped approximately 13,832,500 dosage units of Carisoprodol 350 mg, Butalbital/Caffeine/APA, and Tramadol to Pharmacy A.²

11. Between June 2009 and July 30, 2009, the Respondent shipped approximately 2,208,000 units of Carisoprodol 350 mg, Butalbital/Caffeine/APA, and Tramadol to Pharmacy B.

12. The Respondent admitted to the Oklahoma Board that it did not have a "suspicious order monitoring program or a plan for diversion program". The Respondent also admitted that it did not have a method to determine the types of clients with whom it conducted business.

13. The Oklahoma Board found that the Respondent violated the rules and regulations pertaining to the Oklahoma Pharmacy Act: by failing to establish and maintain adequate controls and systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting; by failing to conduct business at all times in conformity with the Oklahoma Pharmacy Act and the regulations promulgated thereunder and by failing to conduct itself at all times in a manner that will entitle it to the respect and confidence of the community in which the Respondent practices.

14. The Oklahoma Board also found that the Respondent violated Oklahoma

² Pharmacy names will not be disclosed in this document, but will be disclosed to the Respondent upon request to the Administrative Prosecutor.

statutes "by engaging in the sale of drugs to pharmacies licensed by Indian tribes without first procuring a license from the Oklahoma Board".

15. The revocation of the Respondent's wholesaler license by the Oklahoma Board constitutes disciplinary action by a licensing or disciplinary authority for acts that are grounds for disciplinary action under H.O. § 12-601 and § 12-6C-09(b) and Code Md. Regs. tit. 10, § 34.22.05 A (3) (k) and (4).

16. The Respondent's conduct, as determined by the Oklahoma Board, constitutes grounds for disciplinary action under H.O. § 12-601 and § 12-6C-09(b) and under Code Md. Regs. tit. 10, § 34.22.07 B (1) (a).

17. The Respondent's failure to designate a registered agent in Maryland constitutes grounds for disciplinary action under H.O. § 12-601 and Code Md. Regs. tit. 10, § 34.22.04 B (1) (a).

CONCLUSIONS

The Board finds that the Respondent violated H.O. § 12-601; H.O. § 12-6C-09; Code Md. Regs. tit. 10, § 34.22.04 B (1) (a); Code Md. Regs. tit. 10, § 34.22.05 A (3) and (4); and Code Md. Regs. tit. 10, § 34.22.07 B (1) (a).

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is this 18th day of May 2011, a majority vote of the Board hereby:

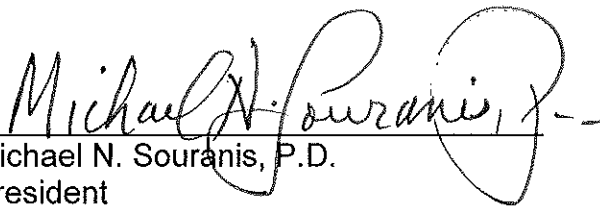
ORDERED that the wholesale distributor permit issued to Gulf Coast Pharmaceuticals, Inc., is hereby **REVOKED**. The Board will not approve, from the Respondent, any future applications for wholesale prescription drug or device distributor

permit or any application for reinstatement of a wholesale prescription drug or device distributor permit; and it is further

ORDERED that for purposes of public disclosure and as permitted by Md. State Govt. Code Ann. § 10-617(h) (2009 Repl. Vol.), 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 a public document pursuant to Md. State Govt. Code Ann. §§ 10-601 *et seq.* (2009 Repl. Vol.).

MAY 18, 2011
Date



Michael N. Souranis, P.D.
President
State Board of Pharmacy

NOTICE OF RIGHT TO APPEAL

Pursuant to Md. Health Occ. Code Ann. § 3-316 (2009 Repl. Vol.), you have a right to take a direct judicial appeal. A Petition for Judicial Review must be filed within thirty (30) days of your receipt of the Final Order and shall be made as provided for judicial review of a final decision, in the Md. State Govt. Code Ann. §§ 10-201 *et seq.* (2009 Repl. Vol.), and Title 7, Chapter 200 of the Maryland Rules.