

STATE OF FLORIDA
BOARD OF PHARMACY

IN RE: PETITION FOR DECLARATORY STATEMENT

UNIQUE PHARMACEUTICALS

FINAL ORDER

This matter came before the Board of Pharmacy (hereinafter the "Board") on February 11, 2009, in Jacksonville, Florida, for consideration of the above-referenced Petition for Declaratory Statement. The Notice of Petition for Declaratory Statement was published on January 23, 2009, in Vol. 35, No. 03, of the Florida Administrative Weekly. Petitioner was present but not represented by counsel.

Petitioner submitted three questions to the Board.

1. Is a wholesale license required for a pharmacy to sell compounded preparations directly to physicians or hospitals?
2. Is a pedigree required for these compounded prescriptions?
3. Is a state controlled substance license for the sale of scheduled medications required?

FINDINGS OF FACTS

1. Petitioner is a pharmacy located in the State of Texas.
2. The petition failed to set forth any particular circumstances to which the referenced rule was to be applied.

CONCLUSIONS OF LAW

1. The Board of Pharmacy has authority to issue this Final Order pursuant to Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

2. Section 120.565, Florida Statutes, reads in part as follows:

(1) Any substantially affected person may seek a declaratory statement regarding an agency's opinion as to the applicability of a statutory provision, or of any rule or order of the agency, as it applies to the petitioner's particular set of circumstances.

(2) The petition seeking a declaratory statement shall state with particularity the petitioner's set of circumstances and shall specify the statutory provision, rule, or order that the petitioner believes may apply to the set of circumstances

3. Rule 28-15.001, Florida Administrative Code states:

A declaratory statement is a means for resolving a controversy or answering questions or doubts concerning the applicability of statutory provisions, rules, or orders over which the agency has authority. A petition for declaratory statement may be used to resolve questions or doubts as to how the statutes, rules, or orders may apply to the petitioner's particular circumstances. A declaratory statement is not the appropriate means for determining the conduct of another person.

4. Because the petition fails to specify or describe Petitioner's specific or particular circumstances, the Board is unable to provide a response.

5. Section 499, Florida Statutes, sets forth the requirements of wholesale permits and pedigree papers.

6. Section 499.002(2), Florida Statutes states:

The department shall administer and enforce this part to prevent fraud, alteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices and cosmetics.

7. Section 499.003(15), Florida Statutes, defines "Department" as the Department of Health.
8. Therefore, the Board of Pharmacy does not have the jurisdiction or authority to answer Petitioner's first two questions.
9. The Board of Pharmacy advised Petitioner that the State of Florida does not have a separate state controlled substance license.

Based on the foregoing, the Board hereby **DENIES** Unique Pharmaceutical's petition for declaratory statement.

DONE AND ORDERED this 4 day of March, 2009.

BOARD OF PHARMACY



Rebecca R. Poston, R.Ph., Executive Director
for Jennifer Lalani, R.Ph., Chair

NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the District Court of Appeal in the Appellate District where the party resides. The Notice of Appeal must be filed within thirty (30) days of rendition of the order to be reviewed.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U. S. Mail to: **Unique Pharmaceuticals**, Timothy Weathers, R.Ph., 5920 South General Bruce Drive, Temple, Texas 76502; and by interoffice mail to: **Deborah B. Loucks**, Assistant Attorney General, PL-01 The Capitol, Tallahassee, Florida 32399-1050, and **Angela Southwell**, Office of the Attorney General, PL-01, The Capitol, Tallahassee, Florida 32399-1050, on March 5, _____, 2009.

Angel Saudez

Deputy Agency Clerk

Petition for Declaratory Statement Before the Board of Pharmacy

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: *Amy R. Conway*
DATE: 1-8-09

From: Unique Pharmaceuticals
Timothy Weathers R.Ph.
5920 S. General Bruce Drive
Temple, Texas 76502
Telephone 254-933-4416
Fax 254-933-0875

Definition of Compounding (64B16-27.700)

The questions that we have are based upon required licensure and procedure to be followed. First: do you require a wholesale license for a pharmacy to sell compounded preparations directly to physicians or hospitals. Second: do you require a pedigree for these compounded preparations, third, do you require a state controlled substance license for the sales of scheduled medications.
Thank you very much for your time.

Timothy Weathers
January 8, 2009

Timothy Weathers