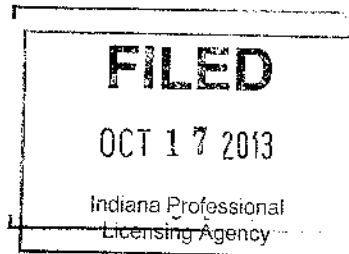


**BEFORE THE INDIANA BOARD
OF PHARMACY
CAUSE NO. : 2013 IBP 0046**

**IN THE MATTER OF THE INDIANA
NON-RESIDENT PHARMACY
PERMIT APPLICATION OF:**

**PHARMACY CREATIONS
PERMIT NUMBER: 64001516A**



FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER

The Indiana Board of Pharmacy ("Board") conducted an administrative hearing on October 7, 2013, in Room W064 of the Indiana Government Center South, 302 West Washington Street, Indianapolis, Indiana, concerning Pharmacy Creations' ("Applicant") petition to review the Board's denial of its application for a non-resident pharmacy permit.

Applicant appeared by John Karolchyk, pharmacist and by counsel, Lyle Hardman of South Bend.

The Board, after considering the evidence presented and taking official notice of its file in this matter, by a vote of 4 to 0, issues the following Findings of Fact, Conclusions of Law and Order:

FINDINGS OF FACT

1. Applicant, whose mailing address is 540 Route 10 West, Randolph, New Jersey 07869, submitted an application to the Board for a permit as a non-resident pharmacy.

2. Karolchyk made a personal appearance before the Board in April 2013 to answer questions about his application. During the dialogue with Board members, it

became evident that Pharmacy Creations had been shipping medications into this state without a permit.

3. Shipping medications into Indiana without being permitted as a non-resident pharmacy is illegal, and the Board denied Pharmacy Creations' application.

4. The Applicant is appealing the decision not to issue a permit.

5. The Applicant received timely and proper notice of the date, time, and location of this hearing pursuant to Ind. Code § 4-21.5-3-20.

6. The Board is empowered to hold this administrative hearing pursuant to the authority of Ind. Code § 25-1-9-9 and Ind. Code ch. 4-21.5-3.

7. Karolchyk acknowledged that his company had shipped drugs into Indiana without a permit for approximately 16 months. He characterized the shipments as a gross oversight on his part and has taken action to assure it will not happen again.

8. Pharmacy Creations is licensed in six other states and those licenses are unencumbered. Pharmacy Creations is a specialty compounding pharmacy that produces medications for ophthalmologists. It supplied four clinics in Indiana.

9. Pharmacy Creations is USP 797 compliant and has passed numerous recent inspections from the Food and Drug Administration, New Jersey Pharmacy Board, and the National Association of Boards of Pharmacy.

10. Karolchyk has been a pharmacist for 23 years, has appeared before Congress to testify about compounding pharmacies, and has taught classes at Rutgers University. Shipping drugs into Indiana without a permit is the only legal problem he has ever had with his practice.

11. The Board concludes that although Pharmacy Creations violated the law in the past, it stands to perform a valuable service for Indiana citizens in the future.

CONCLUSIONS OF LAW

1. Ind. Code § 25 -1-9-16(b) provides that a Board may issue a license on probation if the applicant committed an act for which the applicant could be disciplined.

2. The Applicant shipped drugs into Indiana without a permit. Before shipping into the state a non-resident pharmacy “must register with the board.” Ind. Code § 25-26-17-3.

ORDER

Based upon the foregoing, the Board issues the permit to the Applicant pursuant to Ind. Code § 25-1-9-16(b) as follows:

1. The Applicant’s permit as a non-resident pharmacy will be issued on **INDEFINITE PROBATION**. The Applicant may petition to have the probationary order withdrawn after 16 months from the date of this order.

2. The Applicant’s operation as a non-resident pharmacy shall be governed by the following **TERMS AND CONDITIONS**:

a) Applicant shall keep the Board apprised of its current mailing address, e-mail address, and telephone number at all times.

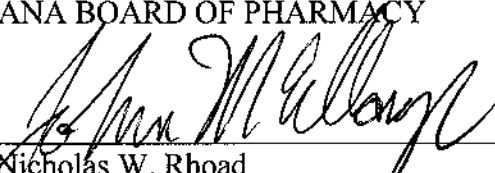
b) Applicant shall not violate any laws regulating the operation of a non-resident pharmacy.

c) Applicant shall notify the Board in writing of any discipline incurred in other states during the duration of its probation, including any relevant criminal or licensing charges pending.

3. The failure of Applicant to comply with the terms of this decision may subject it to a show cause hearing and the imposition of further sanctions.

ISSUED, this 17th day of October, 2013.

INDIANA BOARD OF PHARMACY

By: 

Nicholas W. Rhoad

Executive Director

Indiana Professional Licensing Agency

for

CERTIFICATE OF SERVICE

I certify that a copy of the "Findings of Fact, Conclusions of Law and Order" has been duly served upon:

Pharmacy Creations
540 Route 10 West
Randolph, NJ 07869
Service by U.S. Mail

Lyle Hardman
205 West Jefferson Boulevard
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P.O. Box 4156
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Service by U.S. Mail

10/17/13
Date

Jessi N. Roy
Signature

Indiana Board of Pharmacy
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Explanation of Service Methods

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