

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-48
Nonresident Pharmacy License of)	
)	NOTICE OF HEARING AND
DOWNING LABS, LLC)	STATEMENT OF CHARGES
License No. 4030)	
Respondent.)	

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Downing Labs, LLC ("Respondent"), 4001 McEwen Road, Suite 110, Dallas, Texas 75244, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa nonresident pharmacy license number 4030 is currently active through December 31, 2015.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on January 12, 2016, before the Board. The hearing shall be held during the morning session beginning at 9:00 a.m. and shall be located in the Board conference room located at the Iowa Board of Pharmacy Office, 400 S.W. 8th Street, Suite E, Des Moines, Iowa, 50309-4688.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.11. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

Filing of Pleadings. Pleadings shall be filed with the Board at the following address: Iowa Board of Pharmacy, 400 S.W. 8th Street, Suite E, Des Moines, Iowa, 50309-4688.

Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the Board at hearing.

Pre-hearing Conference. Any party may request a prehearing conference in accordance with 657 IAC 35.15 to discuss issues related to the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. If you need to request an alternative time or date for the hearing, you must comply with the requirements in 657 IAC 35.16. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The Office of Attorney General is responsible for representing the public interest (the State) in this proceeding. Copies of pleadings should be provided to counsel for the State at the following address:

Laura Steffensmeier
Assistant Attorney General
Iowa Attorney General's Office
2nd Floor, Hoover State Office Building
Des Moines, Iowa 50319

Ms. Steffensmeier can also be reached by phone at (515) 281-6690 or by e-mail at laura.steffensmeier@iowa.gov.

Communications. You may contact the Board office at (515) 281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. Board members may only receive information about the case when all parties have notice and the opportunity to participate, such as at the hearing or in pleadings you file with the Board office and serve upon all parties in the case.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2015).

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 147, 155A, and 272C, and 657 IAC 36.

Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 IAC 35.21.

C. CHARGES

COUNT I

OUT-OF-STATE DISCIPLINE

Respondent is charged with violating the pharmacy or drug laws or rules of another state while under the jurisdiction of that state, pursuant to Iowa Code section 155A.13A(3), and 657 IAC 19.10 and 36.1(4)"ad".

COUNT II

FAILURE TO NOTIFY OF DISCIPLINE

Respondent is charged with failing to notify the board within 30 days after a final decision entered by the licensing authority of another state, territory, or country which decision resulted in a license or registration revocation, suspension, or other disciplinary sanction, pursuant to Iowa Code section 155A.13A(3), and 657 IAC 19.10 and 36.1(4)"k".

COUNT III

FAILURE TO SUBMIT APPLICATION FOR PHARMACY LICENSE CHANGES

Respondent is charged with failing to timely submit an application for a change in ownership or name in violation of 657 IAC 8.35(6), pursuant to Iowa Code section 155A.13A(3), and 657 IAC 19.10 and 36.1(4)"u".

D. FACTUAL CIRCUMSTANCES

1. Respondent became licensed as an Iowa nonresident pharmacy in October 2011. When initially licensed, Respondent was operated under the name NuVision Pharmacy, Inc. and was owned by JDB Trust.

2. From approximately May 1, 2013, until approximately January 15, 2014, Ashley Downing was the sole director for NuVision Pharmacy, Inc.

3. On January 15, 2014, Respondent's name changed from NuVision Pharmacy, Inc. to Downing Labs, LLC, and ownership was transferred from JDB Trust to Christopher and Ashley Downing. The Texas State Board of Pharmacy issued Respondent a Texas pharmacy license in the name of Downing Labs on June 25, 2014.

4. In September, 2014, the Food and Drug Administration requested that Respondent issue a recall of all sterile drug products based on findings from an inspection conducted from June 3 through July 16, 2014, and based on testing performed on product lots produced between June 2013 and May 2014. Respondent declined to recall its sterile drug products.

5. On July 31, 2014, the Michigan Board of Pharmacy issued an Order of Summary Suspension, which immediately suspended Respondent's Michigan pharmacy and controlled substance licenses. The suspension was based on Respondent's refusal to initiate a recall of its compounded products. On June 10, 2015, the Michigan Board of Pharmacy issued a Consent Order that dissolved the summary suspension and indefinitely suspended Respondent until such time as it successfully completes an inspection by the National Association of Boards of Pharmacy. To date, Respondent's Michigan pharmacy license has the status "Lapsed – Suspended."

6. On October 14, 2014, the Board received a renewal application from Respondent, which also indicated it was an application for a name change from NuVision Pharmacy, Inc. to Downing Labs, LLC, and an ownership change from JDB Trust to Christopher and Ashley Downing. The application did not disclose any discipline.

7. On February 2, 2015, the Virginia Board of Pharmacy issued an Order of Mandatory Suspension, which immediately suspended Respondent's Virginia non-resident pharmacy registration. The suspension was based on the Michigan Order. To date, Respondent's Virginia non-resident pharmacy registration is suspended.


8. None of the disciplinary orders issued were timely reported to the Board.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 IAC 36.6. If you are interested in pursuing settlement in this matter, please contact Assistant Attorney General Laura Steffensmeier at (515) 281-6690.

F. FINDING OF PROBABLE CAUSE

On this 7th day of November, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



James Miller, Chairperson
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).

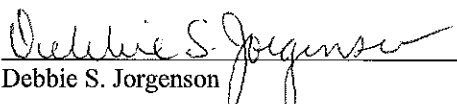
PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:

- | | |
|--|--|
| <input type="checkbox"/> personal service | <input checked="" type="checkbox"/> first class mail |
| <input checked="" type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile |
| | <input type="checkbox"/> other _____ |

on the 5th day of November, 2015.

I declare that the statements above are true to the best of my information, knowledge and belief.



Debbie S. Jorgenson