

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-48
Nonresident Pharmacy License of)	
)	SETTLEMENT AGREEMENT
DOWNING LABS, LLC)	AND FINAL ORDER
f/k/a NUVISION PHARMACY, INC.)	
License Nos. 4030 & 4626)	
Respondent.)	

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2015), and 657 IAC 36.6, the Iowa Board of Pharmacy ("Board") and Downing Labs, LLC, formerly known as NuVision Pharmacy, Inc. ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case currently pending before the Board.

The allegations contained in the Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. The Board filed a Notice of Hearing and Statement of Charges on November 4, 2015.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. Respondent acknowledges that the allegations in the Statement of Charges, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
4. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
5. Respondent acknowledges that it has the right to be represented by counsel on this matter.
6. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.
7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.
8. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.
9. This Order shall not be binding as to any new complaints received by the Board.

10. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

11. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

12. The Board's approval of this Order shall constitute a FINAL ORDER of the Board.

IT IS THEREFORE ORDERED:

13. NuVision Pharmacy agrees to pay a **CIVIL PENALTY** in the amount of five-thousand dollars (\$5000) no later than March 11, 2016. This civil penalty shall be made payable to the Treasurer of Iowa. The civil penalty should be mailed to the Iowa Board of Pharmacy, Attn: Debbie Jorgenson, 400 SW Eighth Street, Suite E, Des Moines, IA 50309. All civil penalty payments shall be deposited into the State of Iowa general fund. This civil penalty is considered discipline against NuVision Pharmacy only and resolves Counts I and II in the Statement of Charges in case 2015-48. Downing Labs is responsible for ensuring that the civil penalty is paid on behalf of NuVision Pharmacy.

14. Effective immediately, nonresident pharmacy license #4030 is hereby cancelled.

15. Effective immediately, Downing Labs shall be issued a new nonresident pharmacy license number. Downing Labs is issued nonresident pharmacy license #4626.

16. Downing Labs, nonresident pharmacy license #4626, is hereby **CITED** for failing to timely submit a new application for pharmacy license changes and **WARNED** that failure to comply with the laws and rules governing the practice of pharmacy in the future could result in further discipline. This citation and warning is considered discipline against Downing Labs only and resolves Count III in the Statement of Charges in case 2015-48.

17. Respondent agrees to follow all federal and state laws and regulations governing the practice of pharmacy and compounding. Respondent agrees to abide by the terms of any agreements with the FDA.

18. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 IAC 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 11 day of January, 2016.



DOWNING LABS, LLC
f/k/a NUVISION PHARMACY, INC.
Respondent

By this signature, Ashley Downing acknowledges s/he is the owner for Downing Labs, LLC f/k/a NuVision Pharmacy, Inc. and is authorized to sign this Settlement Agreement and Final Order on behalf of Downing Labs, LLC f/k/a NuVision Pharmacy, Inc.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 12th day of January, 2016.

Jama Miller
Chairperson
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier
Assistant Attorney General
Licensing & Administrative Law Division
Iowa Department of Justice
Hoover Building, 2nd Floor
Des Moines, IA 50319

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.

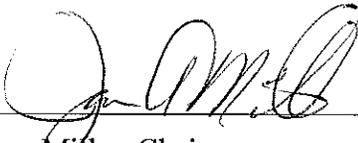
8. None of the disciplinary orders issued were timely reported to the Board.

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).

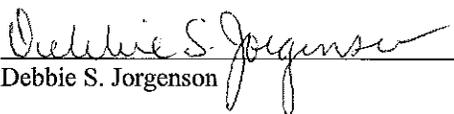
PROOF OF SERVICE

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