

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440
APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
(non-refundable and not transferable money order or cashier's check only)
Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

| | |
|--|---|
| <input checked="" type="checkbox"/> New Wholesaler | <input type="checkbox"/> Ownership Change |
| (Please provide current license number if making changes: WH_____) | |

| | |
|---|--|
| <input type="checkbox"/> Publicly Traded Corporation – Pages 1,2,3,4 | <input type="checkbox"/> Partnership - Pages 1,2,3,6 |
| <input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1,2,3,5a,5b | <input type="checkbox"/> Sole Owner – Pages 1,2,3,7 |
| Please check box for type of ownership and complete correct part of the application. | |

GENERAL INFORMATION

Facility Name: Jubilant DraxImage Inc.

Physical Address: 16751 TransCanada Highway, Kirkland, Quebec, H9H 4J4

Mailing Address: 16751 TransCanada Highway

City: Kirkland State: Quebec Zip Code: H9H 4J4

Telephone: 514-694-8220 Fax: 215-460-8351

Toll Free Number: 1-866-633-5343

E-mail: mrossi@jdi.jubl.com Website: www.draximage.com

Facility Manager: Michael Rossi, President

Professional qualifications and experience of facility manager: Pharmacist and President
Also see attached resume

Types of licensed outlets or authorized persons firm will serve:

Pharmacies Practitioners Hospitals Wholesalers
 Other: Radiopharmacies

Type of Products to be handled or wholesaled by firm:

Legend Pharmaceuticals, Supplies or Devices Hypodermic Devices
 Poisons or Chemicals Veterinary Legend Drugs
 Controlled Substances (include copy of DEA)
 Other: _____

97036

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This page must be submitted for all types of ownership.

Is your company VAWD certified by NABP? Yes No
 (If yes, provide a copy of the certificate.)

Licensed as a Manufacturer by the FDA? Yes No
 (If yes, provide a copy of the FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes No

List the top 4 suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

- 1) JUBILANT HOLLISTERSTIER GP, 16751 TransCanada Highway, Kirkland, Qc, H9H 4J4

| | |
|--------------------------------|---------|
| Name Contract manufacturing | Address |
|--------------------------------|---------|
- 2) NTP RADIOISOTOPES SOC LTD PO BOX 582, PRETORIA SOUTH AFRICA EC

| | |
|--------------------------|---------|
| Business Name ZA 0001 | Address |
|--------------------------|---------|

 develops, produces, and supplies radiochemicals for life science
- 3) OAK RIDGE NATIONAL LABORATORY ONE BETHEL VALLEY ROAD, OAK RIDGE

| | |
|--------------------------------|---------|
| Business Name TN 37831-6158 | Address |
|--------------------------------|---------|

 multi program research laboratory
- 4) NORDION (CANADA) INC 447 MARCH RD. KANATA ON CA K2K 1X8

| | |
|---------------|---------|
| Business Name | Address |
|---------------|---------|

 health science organization that provides market-leading products used for the prevention, diagnosis and treatment of disease

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes No
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? Yes No
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest) or partners with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes No

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This page must be submitted for all types of ownership.

- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest) or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes No
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes No

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.


Original Signature of Person Authorized to Submit Application, no copies or stamps

Michael Rossi 5/15/2017
Print Name of Authorized Person Date

| | | |
|-----------------------|-----------------|-------------------------|
| Board Use Only | Received: _____ | Amount: <u>\$500.00</u> |
|-----------------------|-----------------|-------------------------|

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON-PUBLICLY TRADED CORPORATION

State of Incorporation: Quebec Canada

Parent Company if any: Jubilant Pharma Limited

Corporation Name: Jubilant DraxImage Inc.

Mailing Address: 16751 TransCanada Highway

City: Kirkland State: Quebec Zip: H9H 4J4

Telephone: 514-694-8220 Fax: 514-630-7159

Contact Person: Kevin Brooks, Vice-President Business Development and Strategic Alliances

For any corporation non publicly traded, disclose the following:

1) List any persons to whom the shares were issued by the corporation?

a) Jubilant Pharma Limited 42B Horne Road, Singapore, Singapour, 209066
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 126,201,400

3) What was the price paid per share? 1.00\$

4) What date did the corporation actually receive the cash assets? several dates, see attached

5) Provide a copy of the corporation's stock register evidencing the stock register
above information

See attached

Company Description

Jubilant DraxImage is an FDA-approved manufacturer that distributes radiopharmaceutical diagnostic, therapeutic and monitoring radiopharmaceutical products to authorized users licensed accordingly to receive radioactive materials (i.e. radiopharmacies, hospitals and imaging centers). Jubilant DraxImage does not distribute products to the general public. Our customer service department business hours are 8am and 5pm EST and we manufacture our products during the week, Monday to Friday.

We distribute directly to the licensee (radiopharmacy, hospital or imaging center) and not to the patient. If delivery is delayed beyond the normal delivery time, patients can be rescheduled.

Radiopharmaceuticals dispensed are used for diagnosis of illnesses. In some cases, the illness may be acute and the resulting need for availability of the radiopharmaceutical is critical. Some radiopharmaceuticals are used in one-time therapy applications. Given the short half-life of some of our products, streamlined logistics is essential and shipments are small.

Jubilant DraxImage is a Canadian-based pharmaceutical manufacturing facility occupying 45,000 square feet, compliant with US Food and Drug Administration and Health Canada laws and regulations and the current good manufacturing practices for pharmaceuticals (which include radiopharmaceuticals). We observe well-established and scientifically sound radiation safety principles and regulatory requirements, such as ALARA (As Low As Reasonably Achievable), mandated by the Nuclear Regulatory Commission as well as the Canadian Nuclear Safety Commission, to minimize occupational dose as well as exposure to the public. The preparation, packaging, and distribution of radiopharmaceuticals are also strictly regulated by a number of agencies including the Nuclear Regulatory Commission, the Canadian Nuclear Safety Commission, the Department of Transportation, and the US Boards of Pharmacy.



**JUBILANT
DRAXIMAGE**

5/31

May 26, 2017

Nevada State Board of Pharmacy
431 W. Plum Lane
Reno, Nevada, 89509

Subject: Application for Out of state wholesaler application

Ref.: Request for Expedited Review Process

Dear Sir / Madam:

Enclosed please find our completed application request and supporting documentation for an out of state wholesaler license. Please note that although Jubilant DraxImage Inc. is located in Montreal, Canada, it is a fully owned subsidiary of Jubilant Pharma LLC. with corporate offices in Yardley, Pennsylvania. Jubilant DraxImage is an FDA approved site and we manufacture FDA approved products.

Our President, Michael Rossi, will be present at the July 20th Board of Pharmacy meeting.

We also include an email from Executive Director, Mr. J. David Wuest, R.Ph. which mentions that we may qualify for an out of state wholesale license.

Please do not hesitate to contact the undersigned (514) 630-7061 or by email at nboucherprimiani@jdi.jubl.com should you have any questions or require any further details or clarification.

Many thanks in advance for your review.

Nadia Boucher-Primiani
Legal Coordinator and Executive Assistant

A Jubilant Pharma Company

OUR VALUES



Jubilant DraxImage Inc.
16751 Trans-Canada Highway
Kirkland, Québec, Canada H9H 4J4
Tel: +1-888-633-5343
Fax: +1-866-431-4288
www.draximage.com

Nadia Boucher-Primiani

De: Catherine Saldanha <crsaldanha71@gmail.com>
Envoyé: Tuesday, May 23, 2017 9:17 AM
À: Nadia Boucher-Primiani
Objet: Fwd: Attn: Dave Wuest Deputy Executive Secretary

Hi Nadia - Please include this email with your Nevada submission. I suggest inserting it just after your cover letter.

Thanks,
Catherine

----- Forwarded message -----

From: David Wuest <dwuest@pharmacy.nv.gov>
Date: Wed, May 3, 2017 at 2:29 PM
Subject: RE: Attn: Dave Wuest Deputy Executive Secretary
To: Catherine Saldanha <crsaldanha71@gmail.com>
Cc: Pharmacy Board <pharmacy@pharmacy.nv.gov>, "LARRY L. PINSON" <lpinson@pharmacy.nv.gov>, Paul Edwards <pedwards@pharmacy.nv.gov>

Catherine,

Thank you for your questions. **JDI may qualify for out of state wholesaler licensure.** The current process for Nevada would be to submit an application (available at our website BOP.NV.GOV). The Board would review your license at their Public Meeting, at which time the final decision would be made. I am available for questions at the number below.

Sincerely,

Dave

J. David Wuest R.Ph.

Deputy Secretary

(775) 850-1440

dwuest@pharmacy.nv.gov

From: Pharmacy Board
Sent: Wednesday, April 26, 2017 2:45 PM
To: David Wuest
Subject: FW: Attn: Dave Wuest Deputy Executive Secretary

From: Catherine Saldanha [crsaldanha71@gmail.com]
Sent: Monday, April 24, 2017 3:49 PM
To: Pharmacy Board; Nadia Boucher-Primiani
Subject: Attn: Dave Wuest Deputy Executive Secretary

Dear Mr. Wuest - I am writing on behalf of Jubilant DraxImage, Inc. (JDI). I wanted to follow up on a recent conversation you had with an associate. JDI is an FDA approved Pharmaceutical Manufacturer of their own products seeking licensure as an Out-of-State Wholesaler/Manufacturer with the Nevada Board of Pharmacy. It is my understanding, you agreed to review our request for a license and for your reference, I have attached the most recent inspection and a brief description of the business.

JDI is currently licensed in approximately in 23 States with several applications pending and seven exemptions. I believe with the passing of the Drug Quality and Security Act (DQSA), more and more States are expanding and opening up licensure to businesses like JDI. For example, Virginia and South Carolina who in the past rejected even the thought of a license for a foreign entity has granted JDI the option to apply. South Carolina is requesting a meeting with the Board.

JDI would like an opportunity to meet with the Nevada Board or at least a chance to further discuss a license. Kindly, review the attached and let me know if you have any questions.

Kind Regards,

Catherine