DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21305/S-0042

SUPPLEMENT APPROVAL

Jubilant DraxImage, Inc.
Attention: Aziz R. Nuritdinov
Regulatory Associate, Regulatory
Strategy, Consulting & Submissions
Inc. Research, LLC, US Agent
441 Vine Street, Suite 400
Cincinnati, OH 45202

Dear Mr. Nuritdinov:

Please refer to your Supplemental New Drug Application (sNDA) dated December 4, 2016, received December 8, 2016 and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for HICON (for the preparation of sodium iodide I 131 solution or sodium iodide I 131 capsules), therapeutic, for oral use.

This Prior Approval supplemental new drug application is in reference to FDA's communication dated July 29, 2015 in accordance with the requirements published in the Federal Register in January: *Labeling for Human Prescription Drug and Biological Products*, 71FR 3922, January 24, 2006 and 21CFR 201.56 (b and c), to update your current Prescribing Information to the Physician Labeling Rule (PLR) format.

We also reference your proposed labeling of July 6, 2016.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at: http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Frank Lutterodt, Regulatory Project Manager, at (301) 796-4251.

Sincerely,

{See appended electronic signature page}

Libero Marzella, M.D., Ph.D.
Director,
Division of Medical Imaging Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

CC: Magali Lurquin
Associate Director, Regulatory Affairs
Jubilant DraxImage Inc.
16751 Trans-Canada Highway
Kirlkland, Quebec, Canada, H9H 4J4

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THUY M NGUYEN
07/08/2016

LIBERO L MARZELLA
07/08/2016