DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-305/S-027

SUPPLEMENT APPROVAL

Jubilant DraxImage Inc.
US Agent: Kendle International Inc.
Attention: Hari Nagaradona, Ph.D.
7361 Calhoun Place, Suite 500
Rockville, MD 20855

Dear Dr. Nagaradona:

Please refer to your Supplemental New Drug Application (sNDA) dated June 2, 2011, received June 3, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for HICON Kit for the preparation of Sodium Iodide I 131(Capsules and Solution USP Therapeutic-Oral), Sodium Iodide I 131 Capsules USP, Therapeutic Oral, and Sodium Iodide I 131 Capsules USP, Diagnostic Oral).

This "Prior Approval" supplemental new drug application provides for the following modifications to two presentations of your drug:

HICON™ Kit for the preparation of Sodium Iodide I 131 (Capsules and Solution USP Therapeutic-Oral):

- Change in the formulation to the HICON™ solution
- Reduction of the HICON™ solution shelf life
- Change in the pH specification for HICON™ solution
- Modification of the labeling accordingly

Sodium Iodide I-131 Capsules USP Therapeutic-Oral:

- Change in the formulation of the bulk solution
- Reduction of the bulk solution shelf life
- Reduction of the Capsule shelf life

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 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}

Rafel Dwaine Rieves, M.D.
Director
Division of Medical Imaging Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

CC: Jubilant DraxImage Inc.
Attention: Charles Vachon, M.Sc., MBA
Director, Regulatory Affairs
16751 Trans-Canada Highway
Kirkland, 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/

RAFEL D RIEVES
10/03/2011