



NDA 17-881/S-016

**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 March 21, 2011, received March 24, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Draximage® MAA (kit for the preparation of technetium Tc 99m Albumin Aggregated Injection).

This “Changes Being Effected” supplemental new drug application provides for the name change of the NDA holder from “DRAXIMAGE, a division of DRAXIS Specialty Pharmaceuticals Inc. Kirkland, Quebec, Canada” to Jubilant DraxImage Inc..

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, vial label, post-constitution label, box label), 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).

### **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on March 21, 2011, as soon as they are available, but no more than 30 days after they are printed.

### **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

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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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RAFEL D RIEVES  
09/23/2011