



NDA 17881/S-025

**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 February 5, 2016, received February 8, 2016 and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Draximage® MAA (Kit for the preparation of Technetium Tc99m albumin aggregated injection).

This Prior Approval supplemental new drug application provides for the following:

- a. A change to the Particle Density test acceptance criterion in DRAXIMAGE® MAA finished drug product specifications from  $4 - 8 \times 10^6$  aggregate albumin particles per vial to  $3 - 8 \times 10^6$  aggregate albumin particles per vial.
- b. To change, in addition to the above mentioned change, the Particle Density test acceptance criterion (b) (4) from (b) (4) aggregate albumin particles per vial to (b) (4) (b) (4) aggregate albumin particles per vial.

**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 and with the minor editorial revisions indicated in the enclosed labeling.

**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(1)(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: Hiba Soulaihi  
Senior Project Leader, Regulatory Affairs  
Jubilant DraxImage Inc.  
16751 Trans-Canada Highway  
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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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LIBERO L MARZELLA  
06/09/2016