DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-881/S-010

DRAXIMAGE
A Division of DRAXIS Specialty Pharmaceuticals, Inc.
U.S. Agent: Kendle International Inc.
Attention: Charles Celeste
7361 Calhoun Place
Suite 500
Rockville, MD 20855

Dear Mr. Celeste:

Please refer to your supplemental new drug application dated December 12, 2008, received December 15, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DRAXIMAGE® MAA (kit for the preparation of technetium Tc 99m aggregate albumin) Injection, 2.5 mg/vial.

We acknowledge receipt of your submission dated April 21, 2009.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a change in the storage labeling conditions of the drug product before reconstitution from 2-8°C (36-46°F) to 2-25°C (36-77°F).

We completed our review of this supplemental new drug application, as amended. This supplement is approved.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the submitted labeling on December 12, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 17-881/S-010**."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 17-881/S-010**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Tu-Van Lambert, Regulatory Project Manager, at (301) 796-4246.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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

/s/

Hasmukh Patel

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