DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-305/S-016

DRAXIMAGE, a division of DRAXIS
Specialty Pharmaceuticals Inc.
Attention: Charles Vachon
Associate Director, Regulatory Affairs
16751 TransCanada Highway
Kirkland, Quebec, Canada, H9H 4J4

Dear Mr. Vachon:

Please refer to your supplemental new drug application dated August 27, 2007, received August 28, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the Kit for the Preparation of Sodium Iodide I 131 Capsules and Solution-Therapeutic Oral.

We acknowledge receipt of your submissions dated January 29, 2008.

This supplemental new drug application provides for the new trade name "HICON™, for the Kit for the Preparation of Sodium Iodide I 131 Capsules and Solution - Therapeutic Oral, and labeling changes associated with the new trade name.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

1. Ensure that the established name is at least ½ the size of the proprietary name and that it appears prominently in accordance with 21 CFR 201.10(g)(2).

2. Relocate the radioactive concentration under the established name on both the outer package label and the vial label if possible.

3. Relocate the “Rx Only” statement to the lower portion of the primary display panel of the outer package label.

4. Include the statement “Rx Only” on the lower portion of the primary display panel of the vial label.

5. Relocate the lot number to the lower half of the primary display panel away from the established name if possible.

The final printed labeling (FPL) must be identical to the enclosed package insert, and include the minor editorial revisions indicated to the immediate container and carton labels. These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-305/S-016**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

Please submit one market package of the drug product when it is available.

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 Renee Tyson, Regulatory Project Manager, at (301) 796-2050.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

Kathy Robie-Suh
2/29/2008 04:56:50 PM
signing for Dr. Rafel Dwaine Rieves