DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-305/SLR-005

DRAXIMAGE Inc.
Attention: Charles Vachon
Senior Manager, Regulatory Affairs
167 Autoroute TransCanada Highway
Kirkland, Quebec Canada, H9H 4J4

Dear Mr. Vachon:

Please refer to your supplemental new drug application dated July 6, 2005 received July 8, 2005 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sodium Iodide I 131 Capsule USP, Diagnostic-Oral.

We acknowledge receipt of your submissions dated July 6 and August 19, 2005.

This supplemental new drug application provides for:

1. The addition of instructions on how to use the calendar
2. Change the color of a capsule from blue to orange

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 revision listed below:

1. Under the **"Instructions on how to use the DRAXIMAGE color coded-calendar"** section in the first paragraph please delete light blue and add orange to the first sentence as proposed.

   "DRAXIMAGE Sodium Iodide I 131 Capsules USP, Diagnostic - Oral is manufactured in five different colors (pink, yellow, orange ~~light blue~~, grey and green)."

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert including the color coded calendar and calendar instructions and immediate container 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/SLR-005**." 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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

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}

George Q. Mills, M.D., M.B.A.
Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosures (Labeling)