DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-305

DraxImage, Inc.
Attention : Charles Vachon
Regulatory Affairs Manager
16751 Trans-Canada Highway
Kirkland, Quebec
H9H 4J4, CANADA

Dear Mr. Vachon:

Please refer to your supplemental new drug application dated February 6, 2003, received February 7, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Sodium Iodide I 131 Solution USP.

We acknowledge receipt of your submissions dated May 27, and July 30, and July 31, 2003.

This supplemental new drug application provides draft labeling for the use of Sodium Iodide I 131 Solution and Capsules USP in a high 1000 mCi/mL concentration, for hyperthyroidism and thyroid cancer.

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 dated July 31, 2003.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-305/SLR-001." 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 C. Tyson, Regulatory Project Manager, at (301) 827-7510.

Sincerely,

{See appended electronic signature page}

Sally Loewke, M.D.
Acting Director
Division of Medical Imaging and
Radiopharmaceutical Drug Products
Office of Drug Evaluation III
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/

Sally Loewke
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