DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-305/SCS-002

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

Dear Mr. Vachon:

Please refer to your supplemental new drug application dated July 16, 2004, received July 19, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sodium Iodide I 131 Solution and Capsules.

We acknowledge receipt of your submissions dated July 16, 2004 and November 17, 2004.

This supplemental new drug application provides for the addition of pre-filled capsules for therapeutic use.

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.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert and immediate container and carton labels submitted July 16, 2004.

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/SCS-002." Approval of this submission by FDA is not required before the labeling is used.

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

Sincerely,

{See appended electronic signature page}

Eldon E. Leutzinger, Ph.D.
Chemistry Team Leader
Division of Medical Imaging and
Radiopharmaceutical Drug Products
HFD-160
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Eldon Leutzinger

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