CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-305

Approval Letter(s)

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 August 24, 2000, received August 31, 2000, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Sodium Iodide I-131 Capsules and Solution USP.

We acknowledge receipt of your submissions dated August 9, September 23, October 30, November 21 and 26, December 2 and 11, 2002; January 15, 22, and 24, 2003.

Your submission of July 25, 2002, constituted a complete response to our June 29, 2001, action letter.

This new drug application provides 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. It 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 enclosed labeling text for the, package insert, immediate container and carton labels. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and unapproved.

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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-305." Approval of this submission by FDA is not required before the labeling is used.

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.

We remind you of your postmarketing commitments in your submission dated January 24, 2003. These commitments are listed below:

Submit a labeling supplement within 2 weeks of receiving the action letter for the following changes:

1. On the vials, move the radioactivity symbol from the center to accommodate the addition of radioactivity concentration, and expiration date.

2. On the carton, add the "Rx only" statement.

3. On the package insert, provide pictorial illustrations for preparation instructions for the capsules only.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 C. Tyson, Regulatory Project Manager, at (301) 827-7498.

Sincerely,

{See appended electronic signature page}

Patricia Y. Love, M.D., M.B.A.
Director
Division of Medical Imaging and
Radiopharmaceutical Drug Products
Office of Drug Evaluation III
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/

Patricia Love
1/24/03 03:37:57 PM