# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPROVAL PACKAGE FOR:

## APPLICATION NUMBER

## 21-305

# Correspondence

**********
*** TX REPORT ***
**********

TRANSMISSION OK

| | |
|---|---|
| TX/RX NO | 4164 |
| CONNECTION TEL | 915146949295 |
| SUBADDRESS | |
| CONNECTION ID | |
| ST. TIME | 01/24 11:59 |
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| PGS. SENT | 2 |
| RESULT | OK |

**Food and Drug Administration**
**Center for Drug Evaluation and Research**
**Office of Drug Evaluation ODE III**

# FACSIMILE TRANSMITTAL SHEET

**DATE: January 24, 2003**

| | |
|---|---|
| **To:** Charles Vachon, Regulatory, Regulatory Affairs Manager | **From:** Renee Tyson |
| **Company:** Draximage Inc. | Division of Medical Imaging and Radiopharmaceutical Drug Products |
| **Fax number:** (514) 694-9295 | **Fax number:** (301) 480-6036 |
| **Phone number:** (514) 630-7081 | **Phone number:** (301) 827-7510 |

**Subject:** Phase 4 Commitment

**Total no. of pages including cover:** 1

**Comments:**

**Please send us a fax committing to the following Phase 4 Commitments by 1:00 PM today January 24, 2003.**

**Document to be mailed:** ☐YES ☑NO

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation ODE III

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**Document to be mailed:** ☐ YES ☑ NO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-305

Draximage, Inc.
Attention: Richard J. Flanagan, Ph.D.
President
16751 Autoroute TransCanada Highway
Kirkland, Québec
Canada H9H 4J4

Dear Dr. Flanagan:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Sodium Iodide $I^{131}$ Solution, USP.

We also refer to your letter dated October 30, 2002, containing a request for formal dispute resolution, and your letter dated December 11, 2002, received December 12, 2002, which constituted a response to our request for additional information on this matter.

Your appeal requests a reversal of our decision to require a user fee for your NDA for Sodium Iodide $I^{131}$ Solution, USP, on the basis that there was no change in the indications or uses sought in the NDA from currently approved products.

I have reviewed the documentation for this matter, and agree that you did not intend to expand upon the approved indication for this product. I accept your offer to delete the reference to adolescent dosage and pediatric use sections from your proposed labeling as this information is no longer required for your application.

Therefore, since you're application, submitted under section 505(b)(2) of the Act, does not propose a new indication for a use, a user fee is not required, and your request for a refund will be granted.

Any questions concerning this appeal should be addressed via Ms. Kim Colangelo, Dispute Resolution Project Manager, at (301) 594-5479.

Sincerely,

*(See appended electronic signature page)*

Janet Woodcock, MD
Director
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/

Janet Woodcock
1/10/03 01:55:36 PM

ORIGINAL

DRAXIMAGE

RECEIVED
SEP 24 2002
FDR/CDER

By Fax/By Courier

September 23, 2002

Dr. Kyong Kang
Chief, Project Management Staff
Division of Medical Imaging and
Radiopharmaceutical Drug Products
5600 Fishers Lane
Rockville,
Maryland 20857

NEW CORRESP

N-000-C

RE: Application Fees for NDA 21-305 (Sodium Iodide I 131)

Dear Dr. Kang,

Further to your letter dated September 18, 2002, we wish to inform you that a wire transfer was processed on September 19, 2002. We respectfully request that the review and the user fee clock be reactivated.

Should you have any questions or comments, please, do not hesitate to contact us at 514-630-7081, by fax at 514-694-9295 or by e-mail at Cvachon@Draximage.com.

Sincerely yours,

Charles Vachon, M. Sc.
Regulatory Affairs Manager

c.c. Dr. Richard J. Flanagan, President

DRAXIMAGE Inc.• 16751 Autoroute TransCanada Highway• Kirkland• Québec• Canada H9H 4J4
• Tél. 888-633-5343• 514-630-7043• Fax 514-694-9295• Web Site www.draximage.com

5 pages redacted from this section of the approval package consisted of draft labeling