DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-035/S-018

DRAXIMAGE INC.
Attention: Charles Vachon, Senoir Manager
Regulatory Affairs and Project Management
16751 Autoroute TransCanada Highway
Kirkland, Qu H9H4J4
Canada

Dear Mr. Vachon:

Please refer to your supplemental new drug application dated April 22, 2003, received April 23, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DRAXIMAGE MDP-25 (Technetium Tc 99m Medronate (MDP)).

We acknowledge receipt of your submissions dated and April 22, October 30, December3, 2003 and February 3, 2004.

Your submission of February 3, 2004 constituted a complete response to our August 22, 2003 action letter.

This supplemental application proposes a new formulation.

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 submitted labeling (package insert submitted December 3, 2003, carton labels submitted December 3, 2003 and immediate container label submitted February 3, 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 18-035/S-018." 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 question, call Renee C. Tyson, Regulatory Project Manager, at (301) 827-1503.

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Eldon Leutzinger

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