DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-035/SCM-017

Draximage Inc.
Attention: Charles Vachon, M.Sc.
Regulatory Affairs
16571 Autoroute TransCanada Highway
Kirkland Quebec
Canada H9H 4J4

Dear Mr. Vachon:

Please refer to your supplemental new drug application dated January 4, 2002, received January 8, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MDP Kit (Technetium Tc99m Medronate for injection).

We acknowledge receipt of your submission dated February 11, 2002.

This :Changes Being Effected" supplemental new drug application provides for following:

1. Change in manufacturing site for medronate from Merck Frosst Canada Inc. to Draxis Pharma Inc. (Replacement site).
2. Change in lyophilization equipment.
3. Change in Stopper.
4. Change in color of cap
5. Scale up of batch size from(b)(4)----------
6. Change in filling, lyophiliz----------packaging, labeling, site from Merck Frosst Canada Inc. to Draxis Pharma Inc. (replacement site)
6. Change in testing from Merck Frosst Canada Inc. to Draxis Pharma Inc. (replacement site) and the following contract labs: Draxis Pharm Inc. and (b)(4)----------
7. Updated specifications/methods for raw materials, packaging components, and dosage form to reflect current pharmacoepeial standards as well as format changes to reflect new company name.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert and immediate container and carton labels submitted January 4, 2002.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 supplement NDA 18-511/SCM-007." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Patricia A. Stewart, Regulatory Project Manager, at (301) 827-7510.

Sincerely,

{See appended electronic signature page}

Eldon E. Leutzinger, Ph.D.
Chemistry Team Leader for the
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/

Milagros Salazar
7/3/02 03:44:20 PM
For Eldon Leutzinger