



NDA 17-881/SCM-004

DRAXIMAGE Inc.
Attention: Dr. Richard Flanagan
16751 Autoroute TransCanada Highway
Kirkland, Quebec
Canada H9H 4J4

Dear Dr. Flanagan:

Please refer to your supplemental new drug application dated February 7, 2002, received February 8, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MAA Kit (Technetium Tc99m Albumin Aggregated Injection)

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

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

1. Change in manufacturing site for MAA 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, lyophilizing, inspecting, 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)

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 February 7, 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 17-881/SCM-004." 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
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/s/

Eldon Leutzinger
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