DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-123/S-021

Amersham Health
Attention: Ms. Debora Monshizadegan
Manager, Regulatory Affairs
101 Carnegie Center
Princeton, NJ 08540

Dear Ms. Monshizadegan:

Please refer to your supplemental new drug application dated December 19, 2001, received December 20, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omniscan™ Injection.

We acknowledge receipt of your submission dated December 19, 2001.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of the Oslo Plant as an manufacturing site for the manufacture, labeling, packaging and release of Omniscan™ Injection in pre-filled syringes.

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 submitted final printed labeling (immediate container and carton labels submitted December 19, 2001). Accordingly, the supplemental application is approved effective on the date of this letter. However, we note that the supplement did not document methods and controls for the proper application of the clear plastic syringe labels. Please provide documentation and discussion of these controls in correspondence to this NDA file.

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

Please submit one market package of the drug product when it is available.

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 Tia Harper-Velazquez, Pharm.D., 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

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/s/

Eldon Leutzinger
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