DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-351/SCM-010

Amersham Health
Attention: Fred Longenecker
Director, Regulatory Affairs
101 Carneige Center
Princeton, NJ 08540

Dear Mr. Longenecker:

Please refer to your supplemental new drug application dated May 31, 2002, received June 3, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Visipaque (iodixanol) Injection.

We acknowledge receipt of your submission dated July 12, 2002.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of Amersham Health's Cork, Ireland manufacturing site as manufacturer of Visipaque Injection. It also provides for the adding of the Cork, Ireland site to draft labeling.

We have 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 and with the minor editorial revision changing the manufacture to Amersham Health, Cork, Ireland on the vial, carton and package insert.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert, immediate container and carton labels). These revisions are terms of the approval of this application.

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-351/ SCM-010-CBE-30." 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, HF-2
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 questions, call Renee C. Tyson, Regulatory Project Manager, at (301) 827-7498.

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/

Eldon Leutzinger

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