DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-403/SLR-071

Amersham Health
Attention: David Risley
Director, Marketed Products/Regulatory Affairs
101 Carnegie Center
Princeton, NJ 08540-6231

Dear Mr. Risley:

Please refer to your new drug application (NDA) dated December 18, 2000, received December 20, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hypaque-Cysto® (brand of diatrizoate meglumine).

We acknowledge receipt of your submission dated September 30, 2002.

This "Changes Being Effected" supplemental new drug application provides for the revised immediate container label and the package insert labeling to include the phrase "NOT FOR INTRAVASCULAR USE".

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 following phrases will appear in order on the front page of the products package insert and immediate container label:

NOT FOR INTRATHECAL USE

Not For Intravascular Use

For Retrograde Cystourethrography

The final printed labeling (FPL) must be identical to, and include the revisions indicated above and submitted labeling (package insert submitted December 18, 2002 and immediate container and carton labels submitted December 18, 2002), and must be formatted in accordance with the requirements of 21 CFR 201.66. 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 16-403/SLR-071." 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 Patricia A. Stewart, Regulatory Project Manager, at (301) 827-7496.

Sincerely,

{See appended electronic signature page}

Patricia Y. Love, M.D., M.B.A.
Director
Division of Medical Imaging and Radiopharmaceutical Drug Products
Office of Drug Evaluation III
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/

Patricia Love

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