DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-123\SLR-022 **CBE-0 Supplement**

Amersham Health
Attention: Deborah Monshizadegan
101 Carnegie Center
Princeton, NJ 08540

Dear Ms. Monshizadegan:

Please refer to your supplemental new drug applications dated December 27, 2001, received December 28, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omniscan™.

We acknowledge receipt of your submission dated June 26, 2002.

This "Changes Being Effected" (CBE-0) supplemental new drug application provides for a change in the **PRECAUTIONS** section; **LABORATORY TEST FINDINGS** subsection of the current package insert:

> Asymptomatic, transitory changes in serum iron have been observed. The clinical significance is unknown.
>
> Omniscan interferes with serum calcium measurements with some colorimetric (complexometric) methods commonly used in the hospitals, resulting in serum calcium concentrations lower than the true values. In patients with normal renal function, this effect lasts for 12-24 hours. In patients with decreased renal function, the interference with calcium measurements is expected to last during the prolonged elimination of Omniscan. After patients received Omniscan, careful attention should be used in selecting the type of method used to measure calcium.

We have completed the review of these supplemental applications 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 enclosed labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the copies of final printed labeling (FPL) electronically to this NDA 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 20-123\SLR-022\CBE-0". Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division (HFD-160) and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5600 Fishers Lane, HFD-42
Rockville, Maryland 20857

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 Thuy M. Nguyen, M.P.H., Regulatory Health Project Manager, at (301) 827-7510.

Sincerely,

{See appended electronic signature page}

Patricia Y. Love, M.D., M.B.A.
Director
Division of Medical Imaging and
Radiopharmaceutical Drug Products, HFD-160
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

6/28/02 04:10:08 PM