DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-057/SLR-027

Mallinckrodt Inc.
Attention: Robert F. Ingham
Regulatory Affairs- Imaging
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

Dear Mr. Ingham:

Please refer to your supplemental new drug application dated March 15, 2002, received, March 18, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cysto-CONRAY® (iothalamate meglumine injection USP 43%) and Cysto-CONRAY®II (iothalamate meglumine injection USP 17.2%)

We acknowledge receipt of your submissions dated April 1, June 13 and 26, 2002.

This supplemental new drug application, submitted in conjunction with a supplemental new drug application for NDA 13-295/SLR-060, was submitted as "Changes Being Effected," supplement. These supplements provided for combining the urographic indications of Cysto-CONRAY® with the intravascular indications of CONRAY®43 under the CONRAY®43 name. This combination required new labeling for both CONRAY®43 and Cysto-CONRAY®II. However, as we notified you in our May 14, 2002, letter to these applications, an approved supplement is required for these proposed changes prior to distributing the drug product made with these changes. Therefore, these supplements were reviewed as prior approval supplements. This supplement proposed to eliminate the Cysto-CONRAY® indication from the labeling.

We completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted June 26, 2002).

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 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 17-057/SLR-027." 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

9/13/02 11:52:15 AM