DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-937/20-975/20-976/S-009

Tyco Healthcare
Mallinckrodt
Attention: Edward R. Porter
Manager, Regulatory Affairs
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

Dear Mr. Porter:

Please refer to your supplemental new drug applications dated September 29, 2005 received October 5, 2005 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OptiMARK® (gadoversetamide) Injection 0.5 mmol/mL.

Please also refer to your December 8, 1999 approval letter and to your commitment (No.2) to conduct postmarketing studies of gadoversetamide using expanded clinical electrocardiographic monitoring. Those studies would be conducted over a range of gadoversetamide doses in patients receiving continuous comprehensive electrocardiographic monitoring.

We acknowledge receipt of your submissions dated December 13, 2005, January 23, February 23, March 28, May 24, June 14, July 17, and 28, 2006.

These supplemental new drug applications for OptiMARK® (Gadoversetamide) provide for changes to the **Laboratory Test Interactions** section of the labeling revising the statement on calcium test interference and provide for changes to the **Precautions** section of the labeling removing the statement on "Electrocardiographic Change".

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. Postmarketing commitment No.2 has also been fulfilled.

The final printed labeling (FPL) must be identical to the enclosed labeling, and include the minor editorial revisions indicated. These revisions are terms of the approval of these applications.

Please submit an electronic version of the FPL 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "FPL for approved supplement NDA 20-937/20-975/20976/S-009." Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Medical Imaging and Hematology Products and two copies of both the promotional materials and the package inserts directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 James Moore, Pharm.D., Regulatory Project Manager, at (301) 796-2050.

Sincerely,

{See appended electronic signature page}

Rafel Rieves, M.D.
Deputy Division Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Rafel Rieves

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