DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-937/S-022/20-975/S-023/20-976/S-024

SUPPLEMENT APPROVAL

Covidien/Mallinckrodt, Inc.
Attention: Amy J. Crawford
Senior Regulatory Affairs Product Specialist
675 McDonnell Boulevard
Hazelwood, MO 63042

Dear Ms. Crawford:

Please refer to your Supplemental New Drug Applications (sNDAs) dated February 26 and June 4, 2013, received February 26 and June 4, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for OptiMARK™ (gadoversetamide) Injection and OptiMARK™ Pharmacy Bulk Package (gadoversetamide) Injection.

These "Prior Approval" supplemental new drug applications provide for prescribing information pertaining to the other major risks associated with GBCAs: anaphylaxis/hypersensitivity and acute kidney injury (AKI).

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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, Regulatory Health Project Manager, at (301) 796-1986.

Sincerely,

{See appended electronic signature page}

Ira Krefting, M.D.
Deputy Director for Safety
Division of Medical Imaging Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

JAMES W MOORE
08/26/2013

IRA P KREFTING
08/26/2013