DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 16517/S-0013

SUPPLEMENT APPROVAL

Mallinkrodt Pharmaceuticals Inc.
Attention: Katie Merkel
Regulatory Affairs Product Specialist
675 McDonnell Boulevard,
Hazelwood, MO 63042

Dear Ms. Merkel:

Please refer to your Supplemental New Drug Application (sNDA) dated April 23, 2015, received April, 23, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sodium Iodide I-131 Therapeutic Capsules.

This "Prior Approval" supplemental new drug application proposes additions to the adverse reactions section, specifically under adverse reactions that have been reported with doses of sodium iodide I-131 used in the treatment of malignant disease. Additions are proposed in the following sections:

HIGHLIGHTS OF PRESCRIBING INFORMATION ADVERSE REACTIONS

Adverse Reactions that have been reported with doses of sodium iodide I-131 used in the treatment of malignant disease: *cerebral edema, radiation pneumonitis, and pulmonary fibrosis*.

6. ADVERSE REACTIONS

The following adverse reactions have been reported with doses of sodium iodide I-131 used in the treatment of malignant disease:

Nervous System Disorders: *Cerebral Edema
Injury, poisoning and procedural complications: **Radiation pneumonitis, **Pulmonary fibrosis

*In patients with iodine-avid brain metastases
**In patients with iodine-avid lung metastases

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is 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 Frank Lutterodt, Regulatory Project Manager, at (301) 796-4251.

Sincerely,

{See appended electronic signature page}

Libero Marzella, M.D., Ph.D.
Director
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/

LIBERO L MARZELLA
10/20/2015