DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018321/s-022

SUPPLEMENT APPROVAL

Mallinckrodt Nuclear Medicine LLC
Attention: Katie Merkel
Senior Regulatory Affairs Product Specialist
2703 Wagner Place
Maryland Heights, MO 63043

Dear Ms. Merkel:

Please refer to your Supplemental New Drug Applications (sNDA) dated October 5, 2016, received October 5, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Technescan ™ HDP.

Application	Submission Date	Received Date
NDA 018321/S-022	October 5, 2016	October 5, 2016

This "Prior Approval" supplement provides for revisions to the Prescribing Information that include:

In the Warnings Section:

Addition: "Technetium Tc 99m Oxidronate may cause life threatening hypersensitivity reactions. Have cardiopulmonary resuscitation equipment and personnel available and monitor all patients for hypersensitivity reactions."

In the Overdose Section:

Revision: "In the event of the administration of an overdose with Technescan HDP, encourage patients to drink fluids and void frequently to reduce the radiation dose to the patient."

In the Adverse Reaction Section:

Revision: "Hypersensitivity reactions, including life-threatening reactions, as well as nausea, vomiting and injection site reactions, have been infrequently reported with Technetium Tc 99m Oxidronate use."

In the Preparation for Use Section:

Minor Editorial Change for item # 3: "Shake the vial gently, for approximately 30 seconds, to ensure complete dissolution."

We acknowledge receipt of your amendments dated February 17, 2017, March 13, 2017, and March 30, 2017.

We also refer to your March 13, 2017, agreement [redacted] (b) (4)

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. 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/U CM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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).

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 Su-Lin Sun, PharmD, Regulatory Project Manager, at (301) 796-0036 or email su-lin.sun@fda.hhs.gov .

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:
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
03/31/2017