



NDA 020608/S-034

SUPPLEMENT APPROVAL

GE Healthcare Inc.
Attention: James S. Sullivan
Lead, Regulatory Affairs-New Product Development
100 Results Way
Marlborough, MA 01752

Dear Mr. Sullivan:

Please refer to your Supplemental New Drug Application (sNDA) dated June 20, 2016, received on June 21, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for OMNIPAQUE™ (iohexol) injection imaging bulk package, and OMNIPAQUE™ (iohexol) Injection Pharmacy Bulk Package.

This Prior Approval supplemental new drug application proposes the following changes:

1. The indication for use in CT imaging and all referential text to CT imaging has been removed from the package insert of the Pharmacy Bulk Package (PBP).
2. A new package insert has been provided for the Imaging Bulk Package (IBP). The new IBP label is proposed with only the indication for use in CT imaging. This is based on the existing approved PBP labeling.
3. For use only with an ulrich Transfer Set iodinated contrast media transfer set or other iodinated contrast media transfer set cleared for use with this contrast agent in the Imaging Bulk Package.

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 inserts), 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 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).

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your December 20, 2016, electronic correspondence containing final printed carton and container labels.

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

Sincerely,

{See appended electronic signature page}

Alexander Gorovets, M.D.
Deputy Director
Division of Medical Imaging Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:

Content of Labeling (IBP and PBP)
Carton and Container Labeling (IBP and PBP)

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

/s/

ALEXANDER GOROVETS
12/21/2016