NDA 018956/S-105

SUPPLEMENT APPROVAL

GE Healthcare Inc.
Attention: Alletah Schmidt
Senior Regulatory Affairs Manager US
251 Locke Drive
Marlborough, MA 01752

Dear Ms. Schmidt:

Please refer to your supplemental new drug application (sNDA) dated October 8, 2019, received October 8, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omnipaque (iohexol) injection, 150 mL in single-dose +PLUSPAK (polymer bottle),300 mg of Iodine/mL and 350 mg of Iodine/mL in combination with ulrichINJECT CT motionTM.

We acknowledge receipt of your amendment dated June 18, 2020 which constituted a complete response to our April 7, 2020, action letter.

This Prior Approval supplemental new drug application provides for revisions to the carton and container labeling and the United States Prescribing Information (USPI). Specifically, the following sections of the USPI have been updated:

1. **HIGHLIGHTS, the DOSAGE AND ADMINISTRATION (2)**, has been revised to read, “For CT of Head and Body, OMNIPAQUE may be used with an automated contrast injection system or contrast media management system cleared for use with OMNIPAQUE.”
2. **FULL PRESCRIBING INFORMATION: CONTENTS***, added section 2.8 to include “Instructions for Use with an Automated Contrast Injection System or Contrast Management System for CT of the Head and Body”.
3. **FULL PRESCRIBING INFORMATION**, **DOSAGE AND ADMINISTRATION (2)**, a footnote under Tables 11 and 16 have been added to state, “OMNIPAQUE may be used with an automated contrast injection system or contrast management system cleared for use with OMNIPAQUE [see Dosage and Administration (2.8)]. See device labeling for device indications, additional information, and instructions for use.”

   Section 2.8, “Instructions for Use with an Automated Contrast Injection System or Contrast Management System for CT of the Head and Body”, has been added to state:

- “OMNIPAQUE may be used with an automated contrast injection system cleared for use with contrast media.

  - See above Important Dosage and Administration Instructions for OMNIPAQUE (2.1).
  - See device labeling for information on device indications, instructions for use, and techniques to help assure safe use.
- OMNIPAQUE 300 mg iodine/mL and 350 mg iodine/mL in 150 mL bottles may be used with a contrast media management system cleared for use with OMNIPAQUE 300 mg iodine/mL and 350 mg iodine/mL in 150 mL bottles.
  - See device labeling for information on device indications, instructions for use, and techniques to help assure safe use.
  - Use sterile technique for penetrating the container closure of OMNIPAQUE 300 and 350 and transferring OMNIPAQUE solution. The container closure may be penetrated only one time with a suitable sterile component of the contrast media management system cleared for use with OMNIPAQUE 300 and 350 in 150 mL bottles.
  - Once the OMNIPAQUE 300 and 350 Injection is punctured, do not remove the bottle from the work area during the entire period of use.
  - Maximum use time is 4 hours after initial puncture.
  - Each bottle is for one procedure only. Discard unused portion."

4. Additionally, the carton and containers have been revised to reflect spelling out the word iodine, adding the statement "Not for Intrathecal Use" in regular text, increased prominence for routes of administration and revised statement regarding contrast injector system to read, (b) (4) (b) (4)

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revision listed below.

- **HIGHLIGHTS**, Recent Major Changes date changed to 07/2020
- Revised date changed to 07/2020

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information) 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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 CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, except with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 018956/S-105.** Approval of this submission by FDA is not required before the labeling is used.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

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 Ms. Sharon Thomas, Regulatory Project Manager, at 301-796-1994.

Sincerely,

{See appended electronic signature page}

Libero Marzella, M.D., Ph.D.
Director
Division of Imaging and Radiation Medicine
Office of Specialty Medicine
Center for Drug Evaluation and Research

ENCLOSURE(S):
- Content of Labeling

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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/s/

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