



NDA 020351/S-048
NDA 020808/S-028

SUPPLEMENT APPROVAL

GE Healthcare
Attention: David C Risley
Lead, Marketed Products, USCAN
100 Results Way
Marlborough, MA 01752

Dear Mr. Risley:

Please refer to your Supplemental New Drug Applications (sNDAs) dated September 12, 2018, received on September 12, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Visipaque™ (iodixanol) Injection and Visipaque™ (iodixanol) Injection-Pharmacy Bulk Package.

These Prior Approval supplemental new drug applications provide for the following changes:

NDA Number	020351	020808
Supplement Number	s048	s028
Product Name	Visipaque™ (iodixanol) Injection	Visipaque™ (iodixanol) Injection - Pharmacy Bulk Package
Proposed Changes	Corrected typographical errors related to “comma” punctuations	
Highlights and Table of Content	Reformed Highlights and Tablet of Content (TOC) to allow the full Prescribing Information (FPI) to start at the beginning of its own page.	
1.2 Indications for Use Intravenous Procedures	In both Highlights section and the Full Prescribing Information: 1. Removing “CT Imaging” in the indications for use of excretory urography and peripheral venography 2. Revising bullets points to separate product’s indication and use	
8.4 Pediatric Use	Removing “CT Imaging” phrase in diagnostic examination sentence	
3 DOSAGE FORMS AND STRENGTHS 16 HOW SUPPLIED/STORAGE AND HANDLING	Correct strength unit from 642 milliliters to 652 milligrams. Removed glass vial and bottle containers	

We have completed our review of these supplemental applications, as amended and 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, with the addition of any labeling changes in pending “Changes Being Effectuated” (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 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).

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, Regulatory Project Manager, by 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

ENCLOSURES: Content of Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LIBERO L MARZELLA
03/12/2019 05:14:56 PM