



NDA 22066/S-010

## SUPPLEMENT APPROVAL

GE Healthcare Inc.  
Attention: Alletah Schmidt  
Regulatory Affairs & Labeling  
Project Manager, USCAN  
100 Results Way  
Marlborough, MA 01752

Dear Ms. Schmidt:

Please refer to your supplemental new drug application (sNDA) submitted and received September 13, 2019, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for OMNISCAN™ (gadodiamide) Injection, Pharmacy Bulk Package (PBP).

This Prior Approval supplemental new drug application provides for the conversion of the Prescribing Information for Omniscan Injection, PBP into Physician Labeling Rule (PLR) format as well as voluntary compliance with the Pregnancy, Lactation, and Labeling Rule (PLLR) content and format requirements.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **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 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*.<sup>1</sup>

The SPL will be accessible from publicly available labeling repositories.

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<sup>1</sup> 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>.

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

Sincerely,

*{See appended electronic signature page}*

Libero Marzella, MD, PhD  
Director  
Division of Medical Imaging Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

ENCLOSURE:  
Prescribing Information

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**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.**  
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/s/  
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LIBERO L MARZELLA  
10/23/2019 12:52:55 PM