



NDA 019596/S064, 021037/S037, 019596/S-065  
and 021037/S-038

## **SUPPLEMENT APPROVAL**

Bayer HealthCare Pharmaceuticals Inc.  
Attention: Dolores Fliss  
Deputy Director, Global Regulatory Affairs  
100 Bayer Blvd., P.O. Box 915  
Whippany, NJ 07981

Dear Ms. Fliss:

Please refer to your Supplemental New Drug Application (sNDA) dated January 18 and June 5, 2018, received January 18 and June 5, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Magnevist<sup>®</sup> (gadopentetate dimeglumine) Injection and Magnevist<sup>®</sup> (gadopentetate dimeglumine) Injection Pharmacy Bulk Package.

The Prior Approval supplemental new drug application provides for the conversion of the Prescribing Information to Physician's Labeling Rule (PLR) format and updates to comply with the Pregnancy and Lactation Labeling Rule (PLLR). The "Changes Being Effected" supplemental new drug application provides for a one page versus a two page Medication Guide modification to the labeling.

### **APPROVAL & LABELING**

We have completed our review of these supplemental applications, 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, 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 via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21CFR314.50(l)(1)(i)] in MS Word format, that includes the changes with the revisions listed 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).

### **MARKET PACKAGE**

Please submit one market package of the drug product when it is available to the following address:

Sharon Thomas  
Food and Drug Administration  
Center for Drug Evaluation and Research  
White Oak Building 22, Room: 5483  
10903 New Hampshire Avenue  
Silver Spring, Maryland  
*Use zip code **20903** if shipping via United States Postal Service (USPS).*  
*Use zip code **20993** if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).*

### **PROMOTIONAL MATERIALS**

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above, by fax to 301-847-8444, or electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf> ).

## **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, Senior Regulatory Health Project Manager at: [sharon.thomas@fda.hhs.gov](mailto:sharon.thomas@fda.hhs.gov) or (301) 796-1994.

Sincerely,

*{See appended electronic signature page}*

Libero Marzella, M.D., Ph.D.  
Division Director  
Division of Medical Imaging Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

ENCLOSURES:  
Content of Labeling and Medication Guide

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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  
07/25/2018

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