



NDA 201277/ S-010

**SUPPLEMENT APPROVAL**

Bayer HealthCare Pharmaceuticals  
Julie Pan, M.D., Ph.D., RAC  
Associate Director, Global Regulatory Strategist  
100 Bayer Boulevard, P.O. Box 915  
Whippany, NJ 07981-0915

Dear Dr. Pan:

Please refer to your Supplemental New Drug Application (sNDA) dated February 13, 2015, received February 13, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Gadavist (gadobutrol) Injection, 0.1 mL/kg.

This “Prior Approval” supplemental new drug application provides for changes to the Pharmacy Bulk Package carton and container labels by replacing the phrase: “Multi-dose container” with: “Contains multiple single doses.”

**APPROVAL & LABELING**

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels **and** carton and immediate-container labels submitted on February 13, 2015, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved “NDA 201277/ S-010.”** Approval of this submission by FDA is not required before the labeling is used. Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

### **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, M.D., Ph.D.  
Director  
Division of Medical Imaging Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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LIBERO L MARZELLA  
07/31/2015