



NDA 21-425/S-017

**SUPPLEMENT APPROVAL**

Bayer HealthCare Pharmaceuticals Inc.  
Attention: Michele L. DeBartolo, MPH, RD  
Global Regulatory Affairs  
P. O. Box 1000  
Montville, NJ 07045-1000

Dear Ms. DeBartolo:

Please refer to your supplemental new drug application dated December 23, 2008, received December 31, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ultravist Pharmacy Bulk Packaging, and your resubmission dated April 26, 2010.

We acknowledge receipt of your amendments dated May 21, July 30, September 14 and 23, October 22, November 2, 2009 and June 4, 2010.

This supplemental application proposes use of Ultravist 370 mgI/mL for Intravenous Contrast Enhanced Computed Tomography of the Head and Body.

We have completed our review of this application, 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**

Within 14 days from the date of this letter, please amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (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 structured product labeling (SPL) format that includes the changes approved in this supplemental application.

**LABELING**

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005). 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 Labeling for approved NDA NDA 21-425/S-017.**” Approval of this submission by FDA is not required before the labeling is used.

### **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. PREA expectations do not apply to this application.

### **LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
5600 Fishers Lane, Room 12B05  
Rockville, MD 20857

### **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 Frank Lutterodt, Regulatory Project Manager, at (301) 796-4251.

Sincerely,

*{See appended electronic signature page}*

Rafel Dwaine Rieves, M.D.  
Director  
Division of Medical Imaging Products  
Office of Oncology Drug Products  
Center for Drug Evaluation and Research

Enclosure: Pharmacy Bulk Package Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21425	SUPPL-17	BAYER HEALTHCARE PHARMACEUTICA LS INC	ULTRAVIST(IOPROMIDE)300M GL/ML/370MGL/ML

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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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RAFEL D RIEVES  
06/23/2010