DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-220/S-033 & 21-425/S-017

SUPPLEMENT APPROVAL

Bayer HealthCare Pharmaceuticals Inc.
Attention: Kevin Hibbert, M.D., MPH
Director, U.S. Regulatory Affairs
P. O. Box 1000
Montville, NJ 07045-1000

Dear Dr. Hibbert:

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 Injection (brand of iopromide) and Ultravist Pharmacy Bulk Packaging, and your resubmission dated November 2, 2009.

We acknowledge receipt of your amendments dated May 21, July 30, September 14 and 23, October 22, and December 28, 2009.

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 20-220/S-033 and 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 and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure: Package Insert
Pharmacy Bulk Packaging

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20220	SUPPL-33	BAYER HEALTHCARE PHARMACEUTICALS INC	ULTRAVIST (IOPROMIDE) INJECTION

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RAFEL D RIEVES
12/30/2009