DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDAs 20-220/S-035
21-425/S-019
22-090/S-002

APPROVAL LETTER

Bayer HealthCare Pharmaceuticals
Attention: Michael Koenig
Associate Director - GRA
P.O. Box 1000
Montville, NJ 07045-1000

Dear Mr. Koenig:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product	NDA Number	Supplement Number	Date of Supplement	Date of Receipt
Ultravist® (iopromide) Injection	20-220	S-035	17-May-09	17-May-09
Ultravist (iopromide) Injection Pharmacy Bulk Packaging	21-425	S-019	17-May-09	17-May-09
Eovist® (gadoxetate disodium) Injection	22-090	S-002	15-May-09	15-May-09

These supplemental new drug applications provide for the use of radio-frequency identification label (RFID) on the primary glass containers.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 15, 2009 for NDA 22-090/S-002 and May 17, 2009 for NDAs 20-220/S-035 and 21-425/S-19

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Tu-Van Lambert, Regulatory Project Manager, at (301) 796-4246.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20220	SUPPL-35	BAYER HEALTHCARE PHARMACEUTICALS INC	ULTRAVIST (IOPROMIDE) INJECTION
NDA-21425	SUPPL-19	BAYER HEALTHCARE PHARMACEUTICALS INC	ULTRAVIST(IOPROMIDE)300MGL/ML/370MGL/ML
NDA-22090	SUPPL-2	BAYER HEALTHCARE PHARMACEUTICALS INC	EVOIST INJECTION

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/s/

JAMES D VIDRA
11/13/2009