DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-220/SCP-018

Berlex Laboratories, Inc.
Attention: John Hegarty
Manager, Drug Regulatory Affairs
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000

Dear Mr. Hegarty:

Please refer to your supplemental new drug application dated November 10, 2003, received November 12, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ultravist® (brand of iopromide) Injection.

We also acknowledge receipt of your submissions dated February 18, and March 2, 8, 10 and 11, 2004.

This supplemental new drug application provides for six new packaging presentations of Ultravist® Injection as shown in the following table:

Product	Proposed New Presentations Fill volume / container size
Ultravist 240 mg I/mL	150 mL / 150 mL
Ultravist 300 mg I/mL	30 mL / 30 mL
	75 mL / 100 mL
	125 mL / 150 mL
Ultravist 370 mg I/mL	75 mL / 100 mL
	125 mL / 150 mL

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (immediate container and carton labels submitted November 10, 2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-220/SCP-018". Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Lynn Panholzer, Pharm.D., Regulatory Project Manager, at (301) 827-3132.

Sincerely,

{See appended electronic signature page}

Eldon E. Leutzinger, Ph.D.
Chemistry Team Leader for the
Division of Medical Imaging and
Radiopharmaceutical Drug Products (HFD-160)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

Enclosure

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

/s/

Eldon Leutzinger

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