



NDA 21-425/SLR-001

Berlex Laboratories, Inc.
Attention: Patricia R. Mayer, Ph.D.
Manager
Global Regulatory Affairs
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000

Dear Dr. Mayer:

Please refer to your supplemental new drug application dated September 16, 2002, received September 17, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ultravist[®] (brand of iopromide) Injection Pharmacy Bulk Package.

We also acknowledge receipt of your submissions dated December 19, 2002, and January 16, 2003.

This supplemental new drug application provides the label for a carton box as secondary package for the Ultravist[®] (brand of iopromide) Injection Pharmacy Bulk Package 500ml bottle.

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 submitted labeling (carton labels submitted January 16, 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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-425/SLR-001." Approval of this submission by FDA is not required before the labeling is used.

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, HF-2
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) 827-3247.

Sincerely,

{See appended electronic signature page}

Patricia Y. Love, M.D., M.B.A.
Director
Division of Medical Imaging and Radiopharmaceutical
Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Kyong Kang
1/23/03 12:20:53 PM
Signing for Dr. Patricia Y. Love