DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-220/SLR-008

Berlex Laboratories, Inc.
Attention: Lynn Carmichael
Manager, Advertising and Labeling, Drug Regulatory Affairs
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Carmichael:

Please refer to your supplemental new drug application dated December 9, 1999, received December 14, 1999, 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 March 28, and April 10 and 23, 2003. Your submission of March 28, 2003, constituted a complete response to our September 30, 2002, action letter.

This supplemental new drug application provides for the addition of information to the DRUG INTERACTIONS section of the package insert. Our September 30, 2002, action letter stated that before this supplemental application may be approved, the labeling must be revised in accordance with the approved agreed upon labeling text for NDA 21-425, ULTRAVIST® (brand of iopromide) Injection Pharmacy Bulk Package. The only acceptable differences are those associated with the Pharmacy Bulk Package itself.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 28, 2003.

We remind you of your commitment in your April 23, 2003, letter to make minor editorial revisions as stated in that letter at the time of next printing of the package insert and to report these revisions in the next annual report.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Lynn Panholzer, Pharm.D., Regulatory Project Manager, at (301) 827-3247.

Sincerely,

{See appended electronic signature page}

Florence Houn, M.D., M.P.H.
Acting Division Director
Division of Medical Imaging and
Radiopharmaceutical Drug Products, HFD-160
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

/s/

Sally Loewke
4/25/03 12:48:42 PM
Signing for F. Houn