CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-425

Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-425

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

Dear Dr. Mayer:

Please refer to your new drug application (NDA) dated November 20, 2001, received November 21, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ULTRAVIST® (brand of iopromide) Injection .

We acknowledge receipt of your submission dated November 20, 2001.

This new drug application provides for the use of ULTRAVIST® (brand of iopromide) Injection for:

(1) **Intra-arterial**: ULTRAVIST® Injection (300 mgI\mL) is indicated for cerebral arteriography and peripheral arteriography and ULTRAVIST® Injection (370 mgI\mL) is indicated for coronary arteriography and left ventriculography, visceral angiography, and aortography.

(2) **Intravenous**: ULTRAVIST® Injection (300 mgI\mL) is indicated for contrast enhanced computed tomgraphic (CECT) imaging of the head and body, and excretory urography.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

We remind you of your Letter-of-Commitment of September 20, 2002, agreeing to revise the labeling and labels to incorporate the agreed upon labeling edits. Also, you have agreed to address the CMC comments of September 19, 2002.

The approved agreed upon labeling will be sent to you under a separate cover.

The final printed labeling (FPL) and labels must be identical to the agreed upon draft labeling and labels of September 20, 2002. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 NDA 21-425." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division (HFD-160) and two copies of both the promotional materials and the package insert directly to:

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

Please submit one market package of the drug product when it is available.

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 Thuy M. Nguyen, M.P.H., Regulatory Health Project Manager, at (301) 827-7510.

Sincerely,

/s/

{See appended electronic signature page}

Patricia Y. Love, M.D., M.B.A.
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
9/20/02 04:46:24 PM
Signing for P. Love