DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-037/S-10

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

Dear Ms. Carmichael:

Please refer to your supplemental new drug application dated August 20, 2004, received August 23, 2004, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Magnevist® Pharmacy Bulk Pack, (Gadopentetate Dimeglumine) Injection 0.5mol/L.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of a new shipping configuration for the 100mL presentation.

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

The final printed labeling (FPL) must be identical to submitted labeling (patient package insert submitted, immediate container and carton labels) submitted August 20, 2004.

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 21-037/S-010." 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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

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 CAPT James Moore, Regulatory Project Manager, at (301) 827-6254.

Sincerely,

{See appended electronic signature page}

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

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/s/

Eldon Leutzinger
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