DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-037/S-014

Berlex, Inc.
Attn: Patricia Mayer, Ph.D.
Director, Global Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Dr. Mayer:

Please refer to your supplemental new drug application dated March 10, 2006, received March 13, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Magnevist® Pharmacy Bulk Pack Injection.

We acknowledge receipt of your submission dated March 13, 2006. We also acknowledge our fax dated September 8, 2006 and your responses dated September 11, 12, and 13, 2006.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an amendment to the package insert section of the labeling by adding a statement for patients with renal impairment in the Precaution section.

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.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "FPL for approved supplement NDA 21-037, S-014." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit final SPL of the agreed upon-labeling text.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regiments are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

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/the Division of Medical Imaging and Hematology Products and two copies of both the promotional materials and package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Tiffany Brown, Regulatory Project Manager, at (301) 796-2050.

Sincerely,

{See appended electronic signature page}

Dwaine Rieves, M.D.
Deputy Division Director
Division of Medical Imaging and
Hematology Products
Office of Oncology Drug Products
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/

Rafel Rieves

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