



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-596/S-033

Berlex
Attention: 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 July 21, 2004, received July 22, 2004, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Magnevist®, (gadopentetate dimeglumine) Injection.

We acknowledge receipt of your facsimiles dated January 18, 20, and 21, 2005.

This supplemental new drug application provides for changes to LABORATORY TEST FINDINGS, NURSING WOMEN, CARCINOGENESIS, MUTAGENESIS, AND IMPAIRMENT OF FERTILITY, and PREGNANCY CATEGORY C Sections of the Labeling.

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 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 19-596, S-033." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens 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 Radiopharmaceutical Drug Products 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, HFD-410
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 CAPT James Moore, Regulatory Project Manager, at (301) 827-6254.

Sincerely,

{See appended electronic signature page}

George Mills, M.D., M.B.A.
Division Director
Division of Medical Imaging and
Radiopharmaceutical Drug Products,
HFD-160
Office of Drug Evaluation III
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/

George Mills
1/21/05 04:52:52 PM