NDA 18-869/S-010

Bayer Corporation Pharmaceutical Division
Attention: Frederich K. Sundermann
400 Morgan Lane
West Haven, CT 06516

Dear Mr. Sundermann:

Please refer to your supplemental new drug application dated Feb. 29, 2000, received March 1, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nimotop (nimodipine) Capsules, 30 mg.

We acknowledge receipt of your submissions dated May 1, 2000, May 23, 2000, June 2, 2000, August 10, 2000, and August 11, 2000.

This supplemental new drug application provides for revised labeling that reflects changes in the CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE, and HOW SUPPLIED sections of labeling. The labeling changes are as follows:

1. Under the CLINICAL PHARMACOLOGY section, the paragraph about the mechanism of action of nimodipine was amended, the description of the effect of nimodipine on mortality in the clinical trials was deleted, and changes were made in regard to the description of the clinical trials.

2. In the INDICATIONS AND USAGE section, the indicated patient population has been expanded from those patients with Hunt and Hess Grades I-III to all patients regardless of their post-ictus neurologic condition (i.e., Hunt and Hess Grades I-V).

3. At the end of the HOW SUPPLIED section, the storage statement was updated to conform to current C

We have completed the review of this supplemental 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 supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert text submitted on August 11, 2000).

Please 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 ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999).
For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-869/S-010." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

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 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, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, 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 Merril Mille, R.Ph., Regulatory Management Officer, at (301) 594-5528.

Sincerely,

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research