



NDA 18-869/S-014

Bayer Pharmaceuticals Corporation  
Attention: Mary Ellen Evanich  
400 Morgan Lane  
West Haven, CT 06516

Dear Ms. Evanich:

Please refer to your supplemental new drug application dated December 29, 2005, received December 30, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nimotop (Nimodipine) capsules.

This "Changes Being Effected" supplemental new drug application provides for the addition of a black box warning to warn about medication administration errors with nimodipine and revision of the WARNINGS, PRECAUTIONS, OVERDOSAGE, DOSAGE AND ADMINISTRATION sections of the package insert.

We have completed our review of this application, as amended. It 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 (text for the package insert). 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 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 NDA 18-869/S-014.**" Approval of this submission by FDA is not required before the labeling is used.

As we agreed, you will send a "Dear Health Care Professional" letter informing health care professionals about the inadvertent intravenous (IV) administration of the contents of Nimotop® (nimodipine) 30 mg oral Capsules which has been associated with serious and life-threatening adverse events including death. When the letter is issued, 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  
WO 22, Room 4447  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

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 Katherine Needleman, Regulatory Project Manager at (301) 796-2250.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure: Package Insert

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Russell Katz

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