



NDA 11-790/S-046

Baxter Healthcare Corporation
Attention: Brenda Marczi, PharmD
Senior Director – Regulatory Affairs
95 Spring Street
New Providence, NJ 07974

Dear Dr. Marczi:

Please refer to your supplemental new drug application dated November 7, 2003, received November 10, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Robaxin Injectable (methacarbamol injection, USP), 100 mg/mL.

This “Changes Being Effected” supplemental new drug application provides for revisions to several sections of the label.

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 text and with the minor editorial revisions indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling. These revisions are terms of the approval of this application.

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 11-790/S-046." 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

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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 Ms. Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at 301-827-2090.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, MD, PhD
Acting Director
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
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/s/

Brian Harvey
5/4/04 10:42:12 AM