



NDA 11-011/S-070
NDA 11-011/S-071

Schwarz Pharma, Inc.
Attention: Gary M. Wieczorek
Regulatory Affairs Manager
6140 West Executive Dr.
Mequon, WI 53092-4467

Dear Mr. Wieczorek:

Please refer to your supplemental new drug applications dated April 27, 2001, received May 1, 2001 for supplement S-070 and dated July 2, 2001, received July 3, 2001 for supplement S-071, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for robaxin® (methocarbamol) Tablets, 500 mg and 750 mg.

We acknowledge receipt of your submissions dated March 3, 2003, for both supplements.

Your submissions of March 3, 2003 constituted a complete response to our January 29, 2003 action letter.

These supplemental new drug applications provide for revisions to the **DESCRIPTION, CLINICAL PHARMACOLOGY/Pharmacokinetics, Special Populations – Elderly** sections, and revisions to **HOW SUPPLIED** section.

We completed our review of these applications, as amended. These applications are 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 text for the package insert. These revisions are terms of the approval of these applications.

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 11-011/S-070 and NDA 11-011/S-071. Approval of these submissions 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, HF-2
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).

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If you have any questions, please call Ms. Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at (301) 827-2090

Sincerely,

{See appended electronic signature page}

Lee S. Simon, MD

Director

Division of Anti-Inflammatory, Analgesic

and Ophthalmic Drug Products, HFD-550

Office of Drug Evaluation V

Center for Drug Evaluation and Research

Enclosure: 1

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

Lee Simon
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