DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-589

Schwarz Pharma, Inc.
Attention: Donna K. Multhauf
Director of Regulatory Affairs
6140 W. Executive Drive
Mequon, WI 53902

Dear Ms. Multhauf:

Please refer to your new drug application (NDA) dated December 30, 2002, received December 31, 2002, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for KEMSTRO (baclofen) tablets.

We acknowledge receipt of your submissions dated:

January 17, 2003	May 14, 2003	June 3, 2003	June 19, 2003
August 18,2003	September 22, 2003	September 23, 2003	September 24, 2003
October 3, 2003	October 10, 2003	October 15, 2003	October 16, 2003
October 24, 2003	October 28, 2003	October 29, 2003	

This new drug application provides for the use of KEMSTRO (baclofen) Tablets for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.

We 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,) and submitted labeling (package insert submitted October 16, 2003). 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 21-589**." Approval of this submission by FDA is not required before the labeling is used.

PHASE 4 COMMITMENTS

We remind you of your postmarketing study commitments in your submissions dated October 10, 2003 (Genotoxicity study), October 15, 2003 (HPLC), and October 28, 2003 (Petechiae Study).

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PRECLINICAL – Genotoxicity Study, per ICH Guidelines

Protocol:	*In vitro* Bacterial Mutation Test (AMES), *In vivo* Rodent Micronucleus Test, and *In vitro* Mammalian Chromosome Aberration Test
Final Report Submission:	In the first annual report

CLINICAL – Petechiae Study

Protocol Submission:	No later than the end of March, 2004.

The protocol will include a project timeline, and a review of the protocol will be conducted by the Agency to ensure agreement. Regarding the objective and scope of the study, project updates will be included in the annual reports for the duration of the study. In addition, monitor this adverse event in accordance with postmarketing reporting system.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

We remind you that you must submit patent information on form FDA 3542, *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, within 30 days of the date of this letter as required by 21 CFR 314.53(c)(2)(ii) and 314.53(d)(2) at the address provided by 21 CFR 314.53(d)(4). The form may be obtained at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html. To expedite review of this patent declaration form, we request you submit an additional copy of the form to this application and to the Center for Drug Evaluation and Research "Orange Book" staff at

Food and Drug Administration
Office of Generic Drugs, HFD-610
Orange Book Staff
7500 Standish Place
Metro Park North II
Rockville, MD 20855-2773

We also remind you of your October 28, 2003 agreement to use the following dissolution specifications: Q = (b)(at 15 minutes , using individual tablet data.

Based on the stability data provided, tentative expiration dating periods of 18 months for both strengths packaged in bottles and stored at controlled room temperature (20 - 25°C), and 24 months for both strengths packaged in blisters and stored at controlled room temperature, are granted.

FDA's Pediatric Rule [at 21 CFR 314.55/21 CFR 601.27] was challenged in court. On October 17, 2002, the court ruled that FDA did not have the authority to issue the Pediatric Rule and has barred FDA from enforcing it. Although the government decided not to pursue an appeal in the courts, it will work with Congress in an effort to enact legislation requiring pharmaceutical manufacturers to conduct appropriate pediatric clinical trials. In addition, third party interveners have decided to appeal the court's decision striking down the rule. Therefore, we encourage you to submit a pediatric plan that describes development of your product in the pediatric population where it may be used. Please be aware that whether or not this pediatric plan and subsequent submission of pediatric data will be required depends upon passage of legislation or the success of the third party appeal. In any event, we hope you will decide to submit a pediatric plan and conduct the appropriate pediatric studies to provide important information on the safe and effective use of this drug in the relevant pediatric populations.

The pediatric exclusivity provisions of FDAMA as reauthorized by the Best Pharmaceuticals for Children Act are not affected by the court's ruling. Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products. You should refer to the Guidance for Industry on Qualifying for Pediatric Exclusivity (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request". FDA generally does not consider studies submitted to an NDA before issuance of a Written Request as responsive to the Written Request. Applicants should obtain a Written Request before submitting pediatric studies to an NDA.

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 Neuropharmacological Drug Products and two copies of both the promotional materials and the package insert(s) directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
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 CDR Teresa Wheelous, Sr. Regulatory Management Officer, at (301) 594-2850.

Sincerely,

{See appended electronic signature page}

Russell Katz
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation 1
Center of Drugs 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/

Russell Katz

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