CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

17-351/S-027

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-351/S-027

Schwarz Pharma, Inc.
Attention: Donna K. Multhauf
Associate Director, Regulatory Affairs
P.O. Box 2038
Milwaukee, WI 53201

Dear Ms. Multhauf:

Please refer to your supplemental new drug application dated April 26, 2000, received April 28, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cortifoam (hydrocortisone acetate rectal metered aerosol).

This supplemental new drug application provides for revised draft labeling of the package insert to add a Geriatric Use subsection to the Precautions section.

We have completed the review of this application, as amended, and it is approvable. Before this application may be approved, however, it will be necessary for you to submit final printed labeling (FPL) for the drug. The labeling should be identical in content to the enclosed labeling text for the package insert.

Please submit 20 copies paper copies of the final printed labeling (FPL) of the package insert, ten of which are individually mounted 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 - NDA* (January 1999).

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

Within 10 days after the date of this letter, you are required to amend the supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110.

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ON ORIGINAL

If you have any questions, call Joanne M. Holmes, M.B.A., Clinical Reviewer, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Jonca Bull, M.D.
Acting Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic
Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

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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.

/s/

Jonca Bull
7/3/01 08:58:35 AM

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