CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

17-351 / S-030

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-351/S-030

CBE-30/CBE-0 SUPPLEMENT

Schwarz Pharma
Attention: Donna K. Multhauf
Director of Regulatory Affairs & QA
6140 W. Executive Drive
Mequon, WI 53092

Dear Ms. Multhauf:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Cortifoam Rectal Foam (hydrocortisone acetate)

NDA Number: 17-351

Supplement number: 030

Date of supplement: 5/23/03

Date of receipt: 5/27/03

This supplemental application was created to separate labeling from a chemistry supplemental application.

This supplemental application, submitted as "Supplement - Changes Being Effected in 30 days," in order to provide data to show that the changes in an approved valve has not had an adverse effect on the stability of hydrocortisone in the product.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on July 26, 2003 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be November 27, 2003.

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products , HFD-550
Attention: Division Document Room, N115
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
Attention: Document Room N115

9201Corporate Blvd
Rockville, Maryland 20850

If you have any questions, call Barbara Gould, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Carmen DeBellas, R.Ph.
Chief Project Manager
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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

/s/

Carmen DeBellas
11/17/03 11:52:02 AM