CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-030

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 22-030

APPROVABLE LETTER

Schwarz Biosciences
Attention: Alan Blumberg, Ph.D.
Senior Director, Global Regulatory Affairs
P.O. Box 110167
Research Triangle Park, NC 27709

Dear Dr. Blumberg:

Please refer to your March 17, 2006 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for fesoterodine fumarate, 4 and 8 mg extended release tablets.

We also refer to your submissions dated May 15, 17 and 23, July 20 and 21, August 3, 9, and 31, September 25, October 3, 6, and 27, November 1,16 and 22, 2006; and January 11, 2007.

We completed our review of this application, as amended, and it is approvable. Before the application may be approved, however, it will be necessary for you to address the following:

1. Pre-Approval Inspection (PAI) of your active pharmaceutical ingredient (API) manufacturing facility, Schwarz Pharma Ltd., located in Shannon, Ireland could not be conducted because the site has not been available for PAI during this review cycle, as stated in your letter, dated July 20, 2006.

   Satisfactory inspection of your API manufacturing facility, Schwarz Pharma Ltd., located in Shannon, Ireland is required before this application may be approved.

2. Labeling remains unresolved.

   Reference is made to the revised labeling conveyed to you on January 24, 2007, that will serve as the basis for future discussions. If additional information relating to the safety or effectiveness of this drug becomes available, revision of the January 24, 2007 labeling may be required.

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(b). The safety update should include data from all non-clinical and clinical studies of the drug under consideration regardless of indication, dosage form, or dose level.

1. Describe in detail any significant changes or findings in the safety profile.

2. When assembling the sections describing discontinuations due to adverse events, serious adverse events, and common adverse events, incorporate new safety data as follows:

   - Present new safety data from the studies for the proposed indication using the same format as the original NDA submission.
   - Present tabulations of the new safety data combined with the original NDA data.
   - Include tables that compare frequencies of adverse events in the original NDA with the retabulated frequencies described in the bullet above.
   - For indications other than the proposed indication, provide separate tables for the frequencies of adverse events occurring in clinical trials.

3. Present a retabulation of the reasons for premature study discontinuation by incorporating the drop-outs from the newly completed studies. Describe any new trends or patterns identified.

4. Provide case report forms and narrative summaries for each patient who died during a clinical study or who did not complete a study because of an adverse event. In addition, provide narrative summaries for serious adverse events.

5. Describe any information that suggests a substantial change in the incidence of common, but less serious, adverse events between the new data and the original NDA data.

6. Provide a summary of worldwide experience on the safety of this drug. Include an updated estimate of use for drug marketed in other countries.

7. Provide English translations of current approved foreign labeling not previously submitted.

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 and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with this division to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call Jean Makie, M.S., R.D., Sr. Regulatory Project Manager, at (301) 796-0952.

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D
Director
Office of Drug Evaluation III
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/

Julie Beitz
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