DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-666/S-005
NDA 20-666/S-006

**SUPPLEMENT APPROVAL**

SmithKline Beecham Corporation d/b/a GlaxoSmithKline
Attention: Ms. Debra Hackett
Director, Regulatory Affairs
One Franklin Plaza
200 North 16th Street
Philadelphia, PA 19102

Dear Ms. Hackett:

Please refer to your new drug application (NDA) 20-666 for ALBENZA® (albendazole) Tablets, 200 mg.

**A. Changes Being Effected Labeling Supplement 005**

Please refer to your supplemental new drug application for NDA 20-666/S-005 dated and received April 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ALBENZA® (albendazole) Tablets, 200 mg.

This supplemental new drug application (sNDA) proposes the following revision to the ALBENZA® labeling to update information in the second paragraph of the **OVERDOSAGE** section regarding the use of gastric lavage (~~strikethrough~~ = deletion):

> One overdosage has been reported with ALBENZA in a patient who took at least 16 grams over 12 hours. No untoward effects were reported. In case of overdosage, symptomatic therapy ~~(e.g., gastric lavage and activated charcoal)~~ and general supportive measures are recommended.

This supplemental new drug application also provides for an editorial revision in the **HOW SUPPLIED** section.

**B. Changes Being Effected Labeling Supplement 006**

Please refer to your supplemental new drug application for NDA 20-666/S-006 dated and received, July 9, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ALBENZA® (albendazole) Tablets, 200 mg.

This supplemental new drug application (sNDA) proposes the addition of a new paragraph to the ALBENZA® labeling in the **PRECAUTIONS/**General subsection to identify the potential for albendazole to uncover undiagnosed neurocysticercosis in subjects when treated with ALBENZA® for other conditions as follows (underline = addition):

> Pre-existing neurocysticercosis may also be uncovered in patients treated with albendazole for other conditions. Patients may experience neurological symptoms (e.g. seizures, increased intracranial pressure and focal signs) as a result of an inflammatory reaction caused by death of the parasite within the brain. Symptoms may occur soon after treatment; appropriate steroid and anticonvulsant therapy should be started immediately.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on April 30, 2009 and July 9, 2009.

## CONTENT OF LABELING

To facilitate the transmission of labeling to the National Library of Medicine for public dissemination, please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate these submissions, "**SPL for approved NDA 20-666/S-005 and NDA 20-666/S-006**."

In addition, within 21 days of the date of this letter, amend any pending applications for this NDA with content of labeling in SPL format to include the changes approved in these applications. Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

## LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

> MedWatch
> Food and Drug Administration
> 5600 Fishers Lane, Room 12B05
> Rockville, MD 20857

## REPORTING REQUIREMENTS

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 Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-1600.

Sincerely,

*{See appended electronic signature page}*

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Package Insert

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| NDA-20666 | SUPPL-5 | GLAXOSMITHKLINE | ALBENZA |
| NDA-20666 | SUPPL-6 | GLAXOSMITHKLINE | ALBENZA |

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/s/

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RENATA ALBRECHT
10/20/2009