NDA 20-833

GlaxoWellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709

Attention: Kathleen A. Prodan
Director, Regulatory Affairs

Dear Ms. Prodan:

Please refer to your new drug application (NDA) dated March 30, 1998, received March 31, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flovent Diskus 50 mcg, Flovent Diskus 100 mcg and Flovent Diskus 250 mcg (fluticasone propionate inhalation powder).

We acknowledge receipt of your submissions dated April 29, May 4, 27, and 28, June 5, July 23, October 12, and December 22, 1998, February 15, June 7, 10, 24, and 30, September 13, October 22, November 11, and December 2, and 14, 1999, March 30, April 13, August 25, September 6, 7, 14, 20, 27, 28, and 29, 2000. Your submission of March 30, 2000, constituted a complete response to our December 8, 1999, action letter.

This new drug application provides for the use of Flovent Diskus 50 mcg, Flovent Diskus 100 mcg and Flovent Diskus 250 mcg (fluticasone propionate) Inhalation Powder for the maintenance treatment of asthma as prophylactic therapy in adults and pediatric patients 4 years of age and older. It is also indicated for patients requiring oral corticosteroid therapy for asthma. Many of these patients may be able to reduce or eliminate their requirement for oral corticosteroids over time.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted September 29, 2000, patient's instructions for use and immediate container and carton labels submitted September 28, 2000). 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 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies 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 - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 20-833." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your post marketing commitment specified in your submission dated September 27, 2000. This commitment, along with any completion dates agreed upon, are listed below.

> [ ]. This information will be submitted as a prior approval supplement by January 1, 2001.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your post marketing commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.81(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these post marketing commitments must be clearly designated "Post Marketing Commitments."

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27) for patients < 4 years of age. We are deferring submission of your pediatric studies until July 31, 2003.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sandy Barnes, Chief, Project Management Staff, at (301) 827-1055.

Sincerely,

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research