NDA 20-441/S-002

Astra USA, Inc.
P.O. Box 4500
Westborough, MA 01581-4500

Attention: Dennis Bucceri
Vice President
Regulatory Affairs

Dear Mr. Bucceri:

Please refer to your supplemental new drug application dated October 6, 1997, received October 8, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pulmicort Turbuhaler (budesonide powder for oral inhalation), 200 mcg.

We acknowledge receipt of your submissions dated November 19, 1997, March 13 and October 5, 1998. The user fee goal date for this application is October 8, 1998.

This supplemental new drug application provides for the use of Pulmicort Turbuhaler for once daily dosing.

We have completed the review of this supplemental application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted for the package insert on October 5, 1998, with one additional revision as agreed in your conversation with David Hilfiker, Project Manager, on October 7, 1998.

> The term “asthma stability” will replace “asthma control,” in the second sentence under CLINICAL TRIALS, Patients Receiving PULMICORT TURBUHALER Once Daily subsection.

Although not a Phase 4 commitment, you are highly encouraged to further study the comparative systemic effects of equal nominal daily doses given once daily compared with twice daily administration, including the elucidation of the relative effects of once daily morning dosing versus once daily evening dosing. Particularly, a short term growth study (e.g., a study utilizing knemometry) would be very useful in better defining the risk-benefit considerations of alternate dosing regimens. You are encouraged to consult the Division prior to the initiation of any studies.

Please submit 20 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. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-441/S-002." Approval of this submission by FDA is not required before the labeling is used.

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 send 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-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, contact Mr. David Hilfiker, Project Manager, at (301) 827-1046.

Sincerely yours,

John K. Jenkins, M.D., F.C.C.P.
Director
Division of Pulmonary Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research