DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-340/S-021

Syntex (USA) Inc.
c/o Forest Laboratories
Harborside Financial Center
Plaza Three, Suite 602
Jersey City NJ 07311

Attention: Amy J. Rubin
Director, Regulatory Affairs

Dear Ms. Rubin:

Please refer to your supplemental new drug application dated March 12, 2002, received March 13, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aerobid/Aerobid M (flunisolide) Inhaler System.

This supplemental new drug application provides for the removal of the black box surrounding the warning about the risk of hypothalamic-pituitary-adrenal (HPA) axis suppression when patients are switched from systemic corticosteroids to inhaled corticosteroids.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted March 12, 2002).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may 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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-340/S-021." Approval of this submission by FDA is not required before the labeling is used.

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

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Ladan Jafari, Regulatory Project Manager, at (301) 827-1084.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Division Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

/s/

Badrul Chowdhury

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