DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 30 1997

TRANSMITTED VIA FACSIMILE

Margaret Flory, M.S.
Associate Director, Regulatory Affairs
Forest Laboratories, Inc.
909 Third Avenue
New York, NY 10022

RE: NDA# 18-340
Aerobid/Aerobid-M (flunisolide) Inhaler System
MACMIS ID# 5951

Dear Ms. Flory:

This letter concerns various print promotional materials disseminated by Forest Laboratories, Inc. (Forest) for Aerobid/Aerobid-M (flunisolide) Inhaler System. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed these materials (e.g., journal ad FA177X96) and determined that they contain an unsubstantiated implied efficacy claim for an unapproved use that is false or otherwise misleading. Therefore, these materials violate the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

The photographic representations of an individual engaged in strenuous physical or athletic activity (such as a man in running up outdoor stadium steps with captioned headline "Controlling asthma can be an uphill battle. The strength of Aerobid can make it easier") suggest an unapproved indication for Aerobid (i.e., prevention of exercise-induced bronchospasm or "EIB") that is inconsistent with the approved product labeling. These images misleadingly suggest that Aerobid is effective in a broader range of asthma patients (i.e., those suffering asthma bronchospasm brought on by exercise) than has been demonstrated by substantial evidence.

Forest should cease its dissemination and use of promotional materials that contain this or similar claims by the next printing of these materials, or within 90 days, whichever comes first. Forest's written response should be received no later than November 14, 1997 to the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17-B-20, 5600 Fishers Lane, Rockville, MD 20857.

DDMAC reminds Forest that only written communications are considered official. In all future correspondence regarding this particular matter, please refer to MACMIS ID # 5951 in addition to the NDA number.

Sincerely,

Joan Hankin, JD
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications