



FOI

Food and Drug Administration
Rockville MD 20857

APR 20 1998

TRANSMITTED VIA FACSIMILE

Ernest G. D'Angelo, J.D.
Regulatory Associate
Forest Laboratories, Inc.
909 Third Avenue
New York, NY 10022

RE: NDA# 18-340
Aerobid/Aerobid-M (flunisolide) Inhaler System
MACMIS ID# 6540

Dear Mr. D'Angelo:

As part of its routine monitoring activities, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed promotional materials for Aerobid/Aerobid-M (flunisolide) Inhaler System that feature the tagline claim "(Delivers) Potency where you want it" with and without an accompanying graphic of the human lung. DDMAC has determined that this claim is misleading and is therefore violative of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

DDMAC objects to this tagline as an implied safety claim because it suggests that the clinical response from this orally inhaled corticosteroid is only due to direct local effect rather than an indirect effect through systemic absorption. DDMAC objected to a similar implied safety claim ("Potency that STOPS in the lungs") on October 15, 1997 and November 7, 1997, citing the safety claim's inconsistency with the PRECAUTIONS and DOSAGE and ADMINISTRATION Sections of the Aerobid approved product labeling. On November 26, 1997, DDMAC reminded Forest that promotion of prescription drug products must be consistent with the approved product labeling.

DDMAC requests that further distribution and use of this violative ad and similar promotional materials cease immediately. Forest's written response should be received by DDMAC no later than May 4, 1998, and should include a list of all violative materials as described above and a description of the company's plan to address this issue.

Forest's response should be directed 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

Ernest G. D'Angelo, J.D.
Forest Laboratories, Inc.
NDA# 18-340

Page 2

only written communications are considered official. In all future correspondence regarding this particular matter, please refer to MACMIS ID# 6540 in addition to the NDA number.

Sincerely,

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