



APR 30 1998

TRANSMITTED VIA FACSIMILE

Ms. Terri Monk
Regulatory Affairs Department
Dura Pharmaceuticals Inc.
7475 Lusk Boulevard
San Diego, CA 92121

RE:

Spiros (albuterol sulfate inhalation powder) 140 mcg
MACMIS ID# 6585

Dear Ms. Monk:

As part of its routine monitoring activities, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed a journal advertisement for its Spiros dry powder inhaler (albuterol sulfate inhalation powder) 140 mcg (April 1998 issue of ADVANCE for Managers of Respiratory Care, page 68 section title "At the Pharmacy").

DDMAC has determined that the journal ad is in violation of the Federal Food, Drug, and Cosmetic Act ("Act") and its implementing regulations, because it promotes an unapproved drug by making implied claims of safety and efficacy that have not been demonstrated by substantial evidence (i.e., adequate and well-controlled studies). Sponsors may not make promotional claims of safety or effectiveness about uses that are under investigation (see 21 CFR 312.7(a)).

DDMAC requests that the distribution and use of this violative ad and similar promotional materials cease immediately. Dura's written response should be received no later than May 14, 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.

Dura's response should be directed to the undersigned 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 Dura that only written communications are considered official.

Ms. Terry Monk
Dura Pharmaceuticals Inc.
NDA#: 20-917

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In all future correspondence regarding this particular matter, please refer to MACMIS# ID 6585 in addition to the NDA number.

Sincerely,

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