DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV - 6 1998

TRANSMITTED VIA FACSIMILE

Ms. Kathleen Heffernan
Senior Manager
Regulatory Affairs Department
Dura Pharmaceuticals Inc.
7475 Lusk Boulevard
San Diego, CA 92121

RE: NDA# 20-917
AlSpiros (albuterol sulfate inhalation powder)
MACMIS ID# 7258

Dear Ms. Heffernan:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of a press release issued on November 4, 1998, by Dura Pharmaceuticals, Inc., regarding AlSpiros (albuterol sulfate inhalation powder) that putatively announced the October 30, 1998, "Not Approvable" (NA) letter FDA sent to Dura for this product ("Dura Pharmaceuticals and Spiros Development Corporation II Announce Receipt of FDA 12-Month Review Letter on Albuterol Spiros; Agency requires additional information").

The November 4, 1998, press release is in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations (see 21 CFR 312.7) because the labeling promotes an unapproved drug product (AlSpiros, including inhaler) by making implied claims of clinical safety and effectiveness that have not been demonstrated by substantial evidence (i.e., adequate and well-controlled studies). The overall promotional message of the press release misleadingly minimizes the fact that Dura must conduct a completely new clinical trial program for the redesigned to-be-marketed product. These clinical trials (12 week and one-year open-label) must be conducted prior to FDA's review of new clinical data (as well as other device performance and reliability data) and any further determinations regarding NDA approvability of the AlSpiros.

The press release is misleading because through various speculative conclusions, statements, terminology, and overall tone, the release misleadingly suggests that, notwithstanding the submission of some "additional" information for FDA evaluation, the Agency has reviewed significant clinical evidence for the AlSpiros and has determined that the product will be found

to be safe and effective for use. By omitting material facts, the press release fails to communicate the seriousness of the most substantial deficiencies discussed in the NA letter

DDMAC communicated these concerns to Dura in written comments on November 3, 1998, regarding its proposed press release to announce the Not Approvable letter.

DDMAC requests that the distribution and use of materials containing these and similar misleading claims cease immediately, including but not limited to, its removal from the PRNewswire website. Dura should respond in writing no later than November 20, 1998, 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 Dura that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID# 7258 in addition to the NDA number.

Sincerely,

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