DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

OCT 21 1997

Mr. Dennis J. Bucceri
Vice President, Regulatory Affairs
Astra USA, Inc.
P.O. Box 4500
Westborough, MA 01581-4500

RE: NDA# 20-441
Pulmicort Turbuhaler (budesonide inhalation powder)
MACMIS# 5940

Dear Mr. Bucceri:

The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed promotional materials for Pulmicort Turbuhaler (budesonide inhalation powder) submitted on FDA Form-2253 and has determined that these materials are false, lacking in fair balance, or otherwise misleading and therefore violate the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Lack of Fair Balance: Disclosure of Adverse Events

As DDMAC previously commented on these risk disclosure issues during the Pulmicort proposed launch review (DDMAC letters dated June 24, 1997 and June 27, 1997), various materials lack adequate fair balance of risk information in comparison to the disclosure of efficacy and safety claims.

Misleading Unsubstantiated Implied Clinical Benefit

As DDMAC previously commented on June 24, 1997 and June 27, 1997, use of to make conclusions of clinical significance when no such clinical significance has been demonstrated is misleading. For example,

Comparative Clinical Claims Unsupported by Lung Deposition/Drug Delivery Studies

As DDMAC previously commented on June 24, 1997 and June 27, 1997, various comparative

are misleading because such claims have not been demonstrated by substantial evidence.

Furthermore, as discussed on June 24, 1997, even if presented as a comparative

Safety Claim Unsubstantiated by Sales Data

As DDMAC previously commented on June 24, 1997, the safety claim is false and/or misleading. The claim of based on cannot be substantiated referenced in the promotional materials.

Furthermore, given the overall presentation for the above claim, the footnoted disclaimer does not offset the misleading suggestion of the claim.

Long-Term Safety Graphs and Claims Presentations: Misleading and Lacking Fair Balance

As DDMAC previously commented on June 27, 1997, are misleading because they lack adequate fair balance information. First, is misleading because

Second, is misleading because the

Dissemination of Misleading Claims in Study Article Reprints

As DDMAC previously commented during the Pulmicort proposed launch review on June 30, 1997, DDMAC considers misleading promotional labeling.

Astra's dissemination of promotion is misleading and inconsistent with the Pulmicort Turbuhaler approved product labeling. The dissemination of this

Astra's dissemination of promotion as misleading and inconsistent with the Pulmicort Turbuhale

Astra's dissemination of these promotional

Astra should immediately cease its use of promotional materials that contain these or similar claims or presentations. Astra should respond in writing no later than November 4, 1997. Astra's response should include a list of all similarly violative materials and a description of its method for discontinuing their use.

Astra'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 Astra that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to *MACMIS ID# 5940* in addition to the NDA number.

Sincerely,

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