DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 23 1998

TRANSMITTED VIA FACSIMILE

Ms. Mary Ganssle
Assistant Director
Regulatory Affairs
Astra USA, Inc.
P.O. Box 4500
Westborough, MA 01581-4500

RE: NDA# 20-233
Rhinocort (budesonide) Nasal Inhaler
MACMIS ID# 6221

Dear Ms. Ganssle:

It has come to the attention of the Division of Drug Marketing, Advertising, and Communications (DDMAC) that Astra USA, Inc. (Astra) has disseminated promotional materials (i.e., "sound cards" PM 8295, PM 8298) for Rhinocort (budesonide) Nasal Inhaler that are misleading or otherwise lacking fair balance and therefore violate the Federal Food, Drug, and Cosmetic Act and implementing regulations.

The sound cards lack fair balance because they do not present information relating to the side effects and contraindications and information relating to the effectiveness of Rhinocort. The statement "Titrate to the smallest amount necessary for the control of symptoms" beneath the logo on the inside of the cards is not presented with a prominence and readability reasonably comparable to the presentation of the product claims. Furthermore, these cards do not provide Rhinocort's indication for use, and the footnoted graph citation title ("Budesonide once-daily in seasonal allergic rhinitis") is not adequately presented to meet this disclosure requirement.

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 February 6, 1998. 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 #6221 in addition to the NDA number.

Sincerely,

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