DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Rockville MD 20857

MAY - 5 1999

TRANSMITTED VIA FACSIMILE

Ms. Mary Ganssle
Associate Director, Regulatory Affairs
Astra Pharmaceuticals, L.P.
P.O. Box 4500
Westborough, MA 01581-4500

RE: NDA# 20-233
Rhinocort (budesonide) Nasal Inhaler
MACMIS ID# 7912

Dear Ms. Ganssle:

This letter concerns promotional materials disseminated by Astra Pharmaceuticals, L.P. (Astra) for Rhinocort (budesonide) Nasal Inhaler (i.e., one-page professional journal ad PM-8776, and a professional mailing-postcard PM-8905). The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed these materials and concluded that they lack fair balance and are otherwise misleading. Therefore, they violate the Federal Food, Drug, and Cosmetic Act and implementing regulations.

Fair Balance

The Rhinocort materials present several safety and efficacy claims: "Gentle—Once-Daily Relief", "Mean on rhinitis—Gentle on the nose." The only balancing information appears in significantly smaller type as (at the bottom of the page in the ad and on a separate page in the postcard) and addresses onset of action and time to maximum effect. The pieces lack fair balance because safety information about the incidence of side effects associated with the product are not also disclosed to balance the safety "gentle" and efficacy claims.

"#1 Prescribed Nasal pMDI*"
(* footnote: "IMS of America, Inc., July 1998"—ad; January 1999--postcard)

The "#1 prescribed" marketing claim is misleading because the footnote reference lacks contextual information to clarify the timeframe and source of the information. The reference to "July 1998" or January 1999 does not adequately describe the relevant time period that these data apply to (i.e., the month of July 1998 or from an unstated month to January 1999).

The data source reference "IMS of America" is not adequate to avoid being misleading. The measurement is not defined (i.e., prescriptions issued or refilled versus sales in dollars) and IMS of America provides sales as well as prescription data. Sales data are not adequate to substantiate a "#1 prescribed claim" and the reference for source of data for this claim does not adequately identify the type of prescription data relied upon.

Astra should immediately cease its dissemination and use of all promotional materials for Rhinocort that contain these or similar violations. Astra's written response should be received by DDMAC no later than May 19, 1999, and should list all similarly violative materials and a description of its method for discontinuation.

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. We remind Astra that only written communications are considered official.

In future correspondence regarding this particular matter, please refer to MACMIS ID# 7912 in addition to the NDA number.

Sincerely,

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