DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

MAY 22 1998

Brian Green
Regulatory Affairs Specialist
Regulatory Affairs
Astra USA, Inc.
5 Otis Street
Westborough, MA 01581-4500

RE: NDA 19-941
EMLA Cream (lidocaine 2.5% and prilocaine 2.5%)
MACMIS ID #6680

Dear Mr. Green:

Reference is made to Astra USA, Inc.'s (Astra) April 10, 1998, Form FDA 2253 submission to the Division of Drug Marketing, Advertising and Communications (DDMAC) for EMLA cream. This submission consists of a promotional brochure for EMLA entitled "Dollops '98- A Newsletter for Nurses, Provided by Astra USA, Inc." DDMAC has reviewed this brochure and has determined that it is in violation of the Federal Food, Drug and Cosmetic Act and its implementing regulations.

Specifically, this brochure fails to present any information relating to side effects and contraindications or other risk information. This risk-balancing information should be presented in a manner that is reasonably comparable in prominence and readability as the presentation of information relating to the effectiveness of the drug.

In order to address these objections, DDMAC requests that Astra take the following actions:

1. Immediately discontinue the use of this, and all other promotional materials for EMLA that lack fair balance.

2. Provide to DDMAC, in writing, Astra's intent to comply with #1 above. Your response should be received by June 4, 1998.

3. This response should include a list of all violative promotional materials and Astra's method for discontinuing their use.

If Astra has any questions or comments, please contact 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 17B-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 #6680 in addition to the NDA number.

Sincerely,

Mark W. Askine, R.Ph.
Regulatory Review officer
Division of Drug Marketing,
Advertising and Communications