

NDA 19-941/S-010

Astra, USA, Inc.
50 Otis Street
Westborough, Massachusetts 01581

Attention: Brian A. Green
Regulatory Affairs Specialist

Dear Mr. Green:

Please refer to your supplemental New Drug Application (sNDA) dated May 14, 1998, received May 15, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EMLA Cream (lidocaine 2.5% and prilocaine 2.5 %).

We acknowledge receipt of your submission dated January 27, 1999.

This supplemental New Drug Application (sNDA) provides for the use of EMLA to expand the pediatric indication to children younger than one month of age to birth (with a gestational age of 37 weeks or greater).

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and patient package insert).

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-941/S-010." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient

care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

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MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact David Morgan, Project Manager, at (301) 827-7410.

Sincerely,

Cynthia G. McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug
Products, HFD-170
Office of Drug Evaluation III
Center for Drug Evaluation and
Research