DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-941/S-018

AstraZeneca
1800 Concord Pike,
P.O. Box 8355
Wilmington, DE 19803-8355

Attention: Judy W. Firor
Director, Regulatory Affairs

Dear Ms. Firor:

Please refer to your supplemental new drug application dated October 27, 2006, received October 28, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the EMLA® Cream (lidocaine 2.5% and prilocaine 2.5%)

We acknowledge receipt of your submission dated February 23, 2006.

This supplemental new drug application provides for changes to the prescribing information to clarify dosing instructions and provide risk assessment of genotoxic or carcinogenic effects associated with the use of lidocaine.

We have completed our review of this application, as amended and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-941/S-018**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kimberly Compton, Regulatory Project Manager, at (301) 796-1191.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure