DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 8-816/S-032

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

Attention: Judy Firor
Director, Regulatory Affairs

Dear Ms. Firor:

Please refer to your supplemental new drug application dated July 9, 2003, received July 10, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xylocaine (lidocaine HCl) 2% Jelly.

Reference is also made to your submission dated January 22, 2004, which constituted a complete response to our January 9, 2004, action letter.

This "Changes Being Effected " supplemental new drug application provides for a revised **PRECAUTIONS** section of the package insert. The "**Carcinogenesis, Mutagenesis, Impairment of Fertility"** subsection is revised. Also, all the references to 10 mL and 20 L polypropylene syringes are deleted as these presentations are no longer marketed.

We have completed our review of this application, and it is approved, effective on the date of this letter, with the revisions indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, in the enclosed labeling text for the package insert. These revisions are terms of the approval of this application.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 08-816/S-032." 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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) 827-7410.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bob Rappaport

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