DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-922/S-023

Wyeth Pharmaceuticals
P.O. Box 8299
Philadelphia, PA 19101-8299

Attention: Valerie Heisterkamp
Manager, Global Regulatory Affairs

Dear Ms. Heisterkamp:

Please refer to your supplemental new drug application dated May 19, 2006, received May 22, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lodine® (etodolac capsules and tablets).

We acknowledge receipt of your submission dated November 16, 2006.

This "Changes Being Effected" supplemental new drug application provides for revisions to the package insert to include updates resulting from a routine review of the Lodine® safety database.

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

The final printed (FPL) labeling must be identical to the enclosed labeling text for the Package Insert and the revised Medication Guide.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.go0v/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplement NDA 18-922/S-023."

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Sharon Turner-Rinehardt, Regulatory Project Manager, at (301) 796-2254.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package Insert
Medication Guide

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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