DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-584/S-004
NDA 20-584/S-006
NDA 20-584/S-007

Wyeth Pharmaceuticals, Inc.
Attention: Valerie Heisterkamp
Manager, Worldwide Regulatory Affairs
PO Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Heisterkamp:

Please refer to your supplemental new drug applications dated August 20, 1998, received August 24, 1998 (S-004), September 6, 2000, received September 7, 2000 (S-006 and June 13, 2001, received June 14, 2001 (S-007) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lodine® XL (etodolac extended-release) Tablets.

We acknowledge receipt of your submission dated October 20, 2003 for S-004, S-006 and S-007.

These supplemental new drug applications provide for the following:

1. S-004, inclusion of a Geriatric Use section in the label
2. S-006 and S-007, additional language to the **PRECAUTIONS** and **ADVERSE REACTIONS** section of the label

This supplemental new drug application also provides for draft labeling that incorporates proposed modifications that serve to harmonize the package insert with Lodine® and/or class labeling.

We 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 labeling (FPL) must be identical to enclosed labeling.

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 20-584/S-004, S-006, S-007**." 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 Ms. Jane A. Dean, RN, MSN, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, MD
Director
Division of Anesthesia, Analgesia
and Rheumatology 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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