DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-553/S-035

Wyeth Pharmaceuticals, Inc.
Attention: Mr. Brian D. Schlag
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Mr. Schlag:

Please refer to your supplemental new drug application dated September 1, 2006 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Inderal LA (propranolol hydrochloride) Long-Acting 60, 80, 120, and 160 mg Capsules.

We acknowledge receipt of your submission dated January 25, 2007.

This supplemental new drug application provides for a revision to the approved package insert to indicate that concomitant use of alcohol may increase plasma levels of propranolol.

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

In the **DESCRIPTION** section, the chemical name has been changed from:

2-Propanol, 1-[(1-methylethyl)amino]-3-(1-naphthalenyloxy)-, hydrochloride

To:

2-Propanol, 1-[(1-methylethyl)amino]-3-(1-naphthalenyloxy)-, hydrochloride, (±)

The approval letter dated January 3, 2007 for NDA 18-553/S-034 requested the following chemical name:

2-Propanol, 1-[(1-methylethyl)amino]-3-(1-naphthalenyloxy)-, hydrochloride, (±)-

Please make this correction and submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the submitted labeling dated January 25, 2007 with the minor editorial revisions listed above. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

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, please call:

Ms. Melissa Robb
Regulatory Health Project Manager
(301) 796-1138

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Norman Stockbridge

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