DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-031/S-035

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

SUPPLEMENT APPROVAL

Dear Mr. Schlag:

Please refer to your supplemental new drug application (NDA) dated July 31, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Inderide (propranolol hydrochloride and hydrochlorothiazide) 40/25 and 80/25 mg Tablets.

This supplemental new drug application provides for the addition of the following statement to the **PRECAUTIONS/Drug/Drug Interactions** section of the labeling:

> Both digitalis glycosides and beta-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia.

This supplement also provides for removal of the following statement from the **WARNINGS/Cardiac Failure** section of the labeling:

> The effects of propranolol and digitalis are additive in depressing AV conduction.

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 enclosed agreed-upon electronic labeling text. We will transmit the SPL version of the labeling submitted on July 31, 2007 to the National Library of Medicine for public dissemination.

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

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 Dan Brum, Pharm.D., Regulatory Project Manager, at (301)796-0578.

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

cc: Enclosed Labeling Text

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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