DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 16-418/S-077 and 18-031/S-034

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 applications dated September 1, 2006 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Inderal (propranolol hydrochloride) 10, 20, 40, 60, and 80 mg Tablets (NDA 16-418) and Inderide (propranolol hydrochloride and hydrochlorothiazide) 40/25 and 80/25 mg Tablets (NDA 18-031).

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

These supplemental new drug applications provide 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 these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. The submitted labeling dated January 25, 2007 will be transmitted 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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