DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-031/S-033

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 June 30, 2006 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 revisions to the **PRECAUTIONS** section of the approved package insert to indicate that reports have been received of small placentas and congenital anomalies in neonates whose mothers received propranolol during pregnancy.

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.

1. Revise the proposed storage statement at the end of the package insert from:

   Store at controlled room temperature 20° to 25°C (68° to 77°F).

   To:

   Store at 20°-25°C (68° to 77°F); excursions permitted to 15°- 30°C (59°- 86°F)
   [see USP Controlled Room Temperature]

2. In the second paragraph of the **DESCRIPTION** section, change the first sentence from:

   Inderal (propranolol hydrochloride) is a synthetic beta-adrenergic receptor-blocking agent chemically described as 1-(Isopropylamino)-3-(1-naphthyloxy)-2-propanol hydrochloride.

   To:

   Inderal (propranolol hydrochloride) is a synthetic beta-adrenergic receptor-blocking agent chemically described as 2-Propanol, 1-[(1-methylethyl)amino]-3-(1-naphthalenyloxy)-, hydrochloride, (±)-.

3. In the third paragraph of the **DESCRIPTION** section, change the second sentence from:

   Its molecular weight is 295.81.

   To:

   Its molecular weight is 295.80

4. The subheadings "Propranolol hydrochloride (Inderal®)" and "Hydrochlorothiazide" under the **PRECAUTIONS/General**, **PRECAUTIONS/ Laboratory Tests**, **PRECATUIONS/Drug/Drug Interactions**, **PRECAUTIONS/Drug/Laboratory Test Interactions**, **PRECAUTIONS/Carcinogenesis, Mutagenesis, Impairment of Fertility**, **PRECUATIONS/Pregnancy: Pregnancy Category C**, and **PRECUATIONS/Nursing Mothers** are no longer bolded. You should consider underlining or italicizing in order to make these subheadings more visible in the structured product labeling (SPL) format.

Submit content of labeling [21 CFR 314.50(l)] in SPL format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the submitted labeling dated June 30, 2006 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.

In addition, within 21 days of the date of this letter, amend any pending applications for this NDA with content of labeling in SPL format to include the changes approved in this application.

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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