



NDA 16-418/S-076

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 Inderal (propranolol hydrochloride) 10, 20, 40, 60, and 80 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 revision listed below.

Revise the storage statement at the end of the package insert from:

Store at controlled room temperature 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°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]

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 June 30, 2006 with the minor editorial revision 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

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/s/

Norman Stockbridge
12/29/2006 09:27:28 AM