DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-418/S-073

Wyeth Pharmaceuticals, Inc.
Attention: Caroline M. Henesey, Ph.D.
500 Arcola Road
Collegeville, PA 19426

Dear Dr. Henesey:

Please refer to your supplemental new drug application dated October 25, 2002, 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.

We acknowledge receipt of your submissions dated April 30, 2003; February 13, and August 11 & 16, 2004.

Your submission dated August 16, 2004 constituted a complete response to our April 28, 2003 action letter.

This supplemental new drug application provides for draft labeling text revised by the separation of the prescribing information for propranolol hydrochloride Injectable and Tablets which is currently presented in a common package insert.

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

1. Under PHARMACODYNAMICS AND CLINICAL EFFECTS/ Angina Pectoris, first sentence, the word (b)(4)------ was changed to “episodes.”

2. Under PHARMACODYNAMICS AND CLINICAL EFFECTS/ Hypertrophic Subaortic Stenosis, first sentence, the word (b)(4)-- -------- was changed to “catheterization.”

3. Under DOSAGE AND ADMINISTRATION/ Pheochromocytoma, first sentence, change the term(b)(4)---------- to “blockade” to read as follows:

   The usual dosage is 60 mg Inderal daily in divided doses for three days prior to surgery as adjunctive therapy to alpha-adrenergic blockade.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated above, to the enclosed labeling text for the package insert. These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 16-418/S-073." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Cardio-Renal Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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:

Mr. Daryl Allis
Regulatory Project Manager
(301) 594-5309

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

Abraham Karkowsky
8/18/04 08:13:55 AM