DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 017407/S-034 **SUPPLEMENT APPROVAL**

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Terry Keyser
Manager, BIPI DRA Product Labeling
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877

Dear Ms. Keyser:

Please refer to your supplemental new drug application dated March 13, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Catapres (clonidine hydrochloride) 0.1 mg, 0.2 mg and 0.3 mg Tablets.

We acknowledge receipt of your submission dated October 27, 2009.

Your submission of October 27, 2009, constituted a complete response to our September 28, 2009, action letter.

This "Changes Being Effected" supplemental new drug application provides for labeling revised as follows:

1. Under PRECAUTIONS/Information for Patients, the following information has been added:

   Patients who wear contact lenses should be cautioned that treatment with CATAPRES tablets may cause dryness of eyes.

2. Under PRECAUTIONS, the Pediatric Use subsection has been changed from:

   Safety and effectiveness in pediatric patients below the age of twelve have not been established (see **WARNINGS**, **Withdrawal**).

   To:

   Safety and effectiveness in pediatric patients have not been established in adequate and well-controlled trials (see **WARNINGS**, **Withdrawal**).

3. The ADVERSE REACTIONS section has been substantially revised, primarily to remove incidence rates for the reported reactions and to change the order of the listed reactions. In addition, the following new reactions have been added: delusional perception, paresthesia, salivary gland pain, erectile dysfunction (changed from impotence), accommodation disorder, and decreased lacrimation.

4. A phone number for medical inquiries has been added to the end of the labeling.

5. The revision number and date have been updated.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on October 27, 2009.

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

**REPORTING REQUIREMENTS**

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 Russell Fortney, Regulatory Project Manager, at (301) 796-1068.

Sincerely,

*{See appended electronic signature page}*

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Content of Labeling

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| NDA-17407 | SUPPL-34 | BOEHRINGER INGELHEIM | CATAPRES |

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

/s/

MARY R SOUTHWORTH
11/09/2009