DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 17407/S-036 **SUPPLEMENT APPROVAL**

Boehringer Ingelheim
Attention: Terry Keyser
Drug Regulatory Affairs
900 Ridgefield Road
P.O. Box 368
Ridgefield, CT 06877-0368

Dear Ms. Keyser:

Please refer to your supplemental new drug application dated November 3, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Catapres, (clonidine hydrochloride) 0.1 mg, 0.2 mg, and 0.3 mg Tablets. We also refer to our complete response letter (b) (4).

This supplemental new drug application provides for revisions to the **PRECAUTIONS** section of the package insert, as we requested in our letter dated September 9, 2009. In response to our letter, you proposed the following revision under **PRECAUTIONS, Drug Interactions**:

> Monitor heart rate in patients receiving clonidine concomitantly with agents known to affect sinus node function of AV nodal conduction, *e.g.*, digitalis, calcium channel blockers, and beta-blockers. Sinus bradycardia resulting in hospitalization and pacemaker insertion has been reported in association with the use of clonidine concomitantly with diltiazem or verapamil.

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 and with the minor editorial revisions listed below and indicated in the enclosed labeling. As noted in our complete response letter dated December 2, 2009, remove the following language from the **PRECAUTIONS, Drug Interaction** section of the package insert:

> **Drug Interactions**
> Serious adverse events, including death, have been reported in concomitant use with methylphenidate, although no causality for the combination has been established. The safety of using clonidine in combination with methylphenidate has not been systematically evaluated.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including the revisions indicated above and in the enclosed labeling text for the package insert. These revisions are terms of the NDA approval. For administrative purposes, please designate this submission, "**SPL for approved NDA 17407/S-036**."

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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, R. Ph.
Regulatory Project Manager
(301) 796-1068

Sincerely,

{See appended electronic signature page}

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

Enclosure:
Agreed-upon labeling text

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-17407	SUPPL-36	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
04/07/2010