DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018891/S-025 **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-TTS (clonidine) Trandsdermal Therapeutic System.

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-TTS Transdermal therapeutic system 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 first paragraph of the ADVERSE REACTIONS/Marketing Experience with CATAPRES-TTS section has been changed from:

   Other adverse effects reported since the drug has been marketed are listed below by body system. In this setting, an incidence or causal relationship cannot always be accurately determined. However, none of the events listed below occurred in a frequency greater than 0.5%.

To:

The following adverse reactions have been identified during post-approval use of CATAPRES-TTS transdermal therapeutic system. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate reliably their frequency or establish a causal relationship to drug exposure. Decisions to include these reactions in labeling are typically based on one or more of the following factors: (1) seriousness of the reaction, (2) frequency of reporting, or (3) strength of causal connection to CATAPRES-TTS transdermal therapeutic system.

4. 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, sleep disorder (changed from insomnia), salivary gland pain, erectile dysfunction (changed from impotence), accommodation disorder, and decreased lacrimation.

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

6. Minor editorial changes have been made throughout the document.

7. 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-18891	SUPPL-25	BOEHRINGER INGELHEIM	CATAPRES TTS

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
11/13/2009