**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-891/S-024

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Ms. Kelly S. Billingham
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877

Dear Ms. Billingham:

Please refer to your electronic supplemental new drug application dated February 6, 2006, received February 7, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Catapres-TTS® (clonidine) 0.1, 0.2, & 0.3 mg Transdermal Patch.

This supplemental new drug application provides for draft labeling as requested in our supplement request letter dated December 5, 2005, as follows:

1. Package Insert
   Under PRECAUTIONS, the following new sub-section was added:

   > MRI
   > Skin burns have been reported at the patch site in several patients wearing an aluminized transdermal system during a magnetic resonance imaging scan (MRI). Because the CATAPRES-TTS PATCH contains aluminum, it is recommended to remove the system before undergoing an MRI.

2. Patient Instructions
   The following precautionary statements were added at the end of the General Information section:

   > Skin burns have been reported at the patch site in several patients wearing an aluminized transdermal system during a magnetic resonance imaging scan (MRI). Because the CATAPRES-TTS PATCH contains aluminum, it is recommended to remove the system before undergoing an MRI.

3. Carton and Pouch Labels
   The following statement was added to the front of both the carton and pouch labels:

   > To avoid possible burns, remove the Catapres-TTS® patch before undergoing an MRI (magnetic resonance imaging) procedure.

In addition, the following editorial revisions were noted:

1. A hyphen was added in the list of dosage strengths noted at the beginning of the package insert to read "CATAPRES-TTS® -1, CATAPRES-TTS® -2, and CATAPRES-TTS® -3."

2. The statement “Rx only” was moved from the end of the package insert to immediately before the Prescribing Information.

3. The drug product name was changed from “CATAPRES-TTS” to “CATAPRES-TTS transdermal therapeutic system” throughout the package insert and patient instructions.

4. The established drug product name, clonidine, was included for the first reference to the drug product on each page of the package insert and patient instructions to read as “CATAPRES-TTS® (clonidine) transdermal therapeutic system”.

5. All references to other sections of the package insert were revised to include the reference as part of the sentence rather than a separate statement following the sentence, i.e., “(See Release Rate Concept)” was changed to “(see Release Rate Concept).”

6. Under DESCRIPTION, System Structure and Components, second paragraph, the text “and aluminum” was added to the description of the first of four layers.

7. Under PRECAUTIONS, Pregnancy, the subsection “Teratogenic Effects” was changed from “italics” to “bold” text.

8. Throughout the package insert, all secondary subheadings were followed by a colon, i.e., ADVERSE REACTIONS, Marketing Experience with CATAPRES-TTS, Body as a Whole:.”

9. Under HOW SUPPLIED, the information for the 3 dosage formulations were reorganized from 2 to 1 sentence to read, “CATAPRES-TTS-1, CATAPRES-TTS-2, and CATAPRES-TTS-3 are supplied as 4 pouched systems and 4 adhesive covers per carton.” In addition, the NDC numbers for the corresponding dosages were deleted from the sentence noted above and added to the chart that lists all approved dosages.

10. The “Manufactured by:” and “Distributed by:” information was reorganized in a list format rather than in a single line format for both the package insert and patient instructions.

11. Copyright date, Revised date, and internal coding information were updated.

12. Under PATIENT INSTRUCTIONS, Instructions for Disposal, the all capital letters and bold text were retained for the phrase “**KEEP OUT OF REACH OF CHILDREN**” as requested in our approval letter of August 13, 2004 for supplement # 022.

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 submitted on February 6, 2006.

The final printed labeling (FPL) must be identical to the labeling (package insert, patient instructions, and immediate container and pouch labels) submitted on February 6, 2006.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 18-891/S-024**." Approval of this submission by FDA is not required before the labeling is used.

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please submit one market package of the drug product when it is available.

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. Denise Hinton, Regulatory Project Manager, at (301) 796-1090.

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

---

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

---

/s/

---

Norman Stockbridge

4/13/2006 10:55:12 AM