NDA 21-073/S-020

Takeda Pharmaceuticals North America, Inc.
Attention: Mary Jo Pritza, MPH, PharmD.
Regulatory Affairs Manager
475 Half Day Road, Suite 500
Lincolnshire, IL 60069

Dear Ms. Pritza:

Please refer to your supplemental new drug application dated January 24, 2003, received January 27, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actos® (pioglitazone HCl) Tablets, 15 mg, 30 mg and 45 mg.

We acknowledge receipt of your submissions dated July 22, August 13, and November 3, and 7, 2003.

This supplement provides for documentation to support multiple labeling changes to the **CLINICAL PHARMACOLOGY** section, (**Clinical Studies** subsection to include revisions of Actos in combination with metformin, a sulfonylurea, or insulin), **WARNINGS, PRECAUTIONS, ADVERSE REACTIONS**, and **DOSAGE and ADMINISTRATION** sections, of the package insert.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted on November 26, 2003.

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 21-073/S-020." 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, 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 Ms. Jena Weber, Regulatory Project Manager, at 301-827-6422.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure (package insert labeling – 30 pages)

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

/s/

David Orloff

11/26/03 04:07:23 PM