



NDA 21-073/S-031

Takeda Global Research & Development Center, Inc.
Attention: Mary Jo Pritza, MPH, Pharm.D.
Associate Director, Regulatory Affairs
One Takeda Parkway
Deerfield, IL 60015

Dear Ms. Pritza:

Please refer to your supplemental new drug application dated June 1, 2007, received June 4, 2007, 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 submission dated August 13, 2007.

This supplemental new drug application proposes labeling revisions to add a **BOXED WARNING** to more prominently discuss the risks for congestive heart failure, a statement to the **CONTRAINDICATIONS** section to state that initiation of pioglitazone is contraindicated in patients with New York Heart Association (NYHA) Class III and IV heart failure, and changes to the **WARNINGS, PRECAUTIONS**, and **DOSAGE AND ADMINISTRATION** sections.

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.

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)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert (package insert submitted August 13, 2007)). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-073."

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 301-796-1306.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure (package insert)

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

/s/

Mary Parks
8/14/2007 03:19:04 PM