



NDA 21-073/S-033

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

Dear Dr. Pritza:

Please refer to your supplemental new drug application dated November 6, 2007, received November 7, 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 April 28, 2008.

This supplemental new drug application provides for a patient package insert (PPI).

We have 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 attached labeling (text for the patient package insert) submitted April 28, 2008.

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) submitted September 6, 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  
Suite 12B05  
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 301-796-1306

Sincerely,

*{See appended electronic signature page}*

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

Enclosure (PPI)

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Mary Parks  
5/7/2008 10:55:59 AM