



NDA 021073/S-040

SUPPLEMENT APPROVAL

Takeda Pharmaceuticals North America, Inc.
Attention: Jessie Y. Lee, Ph.D., RAC
Manager, Regulatory Affairs
One Takeda Parkway
Deerfield, IL 60015

Dear Dr. Lee:

Please refer to your Supplemental New Drug Application (sNDA) dated April 22, 2010, received April 23, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Actos (pioglitazone HCl), 15 mg, 30 mg, and 45 mg Tablets.

This “Changes Being Effected” supplemental new drug application provides for the 30-count sample container bottle labels for all strengths inadvertently omitted from supplement 037, approved on September 9, 2009. The bottle labels have been updated to include the following statement:

Dispense with Medication Guide available in package insert or at www.actos.com

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

Please submit these labels electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” For administrative purposes, designate this submission “**Product Correspondence – Final Printed Container Labels for approved NDA 21-073/S-040.**” Approval of this submission by FDA is not required before the labeling is used.

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 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

Enclosures: Sample container labels for the 30-count bottles of the 15 mg, 30 mg, and 45 mg tablets

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21073	SUPPL-40	TAKEDA PHARMACEUTICA LS NORTH AMERICA INC	ACTOS (PIOGLITAZONE HCL)15/30/45MG TABS

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/s/

MARY H PARKS
07/29/2010