



NDA 021842/S-012

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 ACTOPLUS MET (pioglitazone HCl plus metformin HCl), 15 mg/500 mg and 15 mg/850 mg.

We also refer to your amendment dated July 30, 2010.

This “Changes Being Effected” supplemental new drug application provides for the 60-count sample container bottle labels for each strength inadvertently omitted from supplement 009, approved on September 14, 2009. The bottle labels have been updated to include the following statement:

***Dispense with Medication Guide available in package insert or at
www.actoplusmet.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 021842/S-012.**” 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 60-count bottles

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21842	SUPPL-12	TAKEDA GLOBAL RESEARCH DEVELOPMENT CENTER INC	ACTOPLUS-MET (METFORMIN/PIOGLITAZONE HCL

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/s/

MARY H PARKS
08/06/2010