CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-024

OTHER REVIEW(S)

Division of Metabolism and Endocrinology Products

REGULATORY PROJECT MANAGER REVIEW

Application Number: NDA 22-024

Name of Drug: Actoplus Met XR (pioglitazone HCl + metformin HCl) Fixed-Dose Combination Tablets

Sponsor: Takeda Global Research & Development Center, Inc.

Submission Date (AZ): April 30, 2008

Material Reviewed:

Submission Date	Receipt Date	Document Type
December 10, 2008	December 11, 2008	Revised carton & container labels
March 25, 2009	March 26, 2009	Revised PI and Med Guide

Background and Summary

This new drug application provides for the use of ACTOPLUS MET XR as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are already treated with pioglitazone and metformin or who have inadequate glycemic control on pioglitazone alone or metformin alone.

An approvable letter was issued to this NDA file on February 2, 2007. Takeda responded with a major amendment (AZ) on April 30, 2008.

Final carton and container labels were submitted on December 10, 2008. These were found acceptable as noted in the review from DMEPA dated December 17, 2008.

The agreed-upon FDA/Takeda PI and Med Guide labels were submitted on March 25, 2009.

Review:

Package Insert: Acceptable; FDA comments sent to Takeda on 3/18/09; compared to revised submission from company dated 3/25/09. Takeda accepted and inserted changes as requested. No discrepancies noted.

Med Guide Acceptable; FDA comments sent on 3/18/09, compared to revised submission from Takeda dated 3/25/09. No discrepancies noted from FDA requested version. Takeda accepted and inserted changes as we requested.

Carton & Container Labels: Acceptable as per DMEPA review dated 12/17/08.

Tradename: Acceptable as per DMEPA review dated 4/30/09.

Conclusion:

An approval letter issued for NDA 22-024. SPL was submitted on April 1, 2009. This will be forwarded to NLM.

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

/s/

Jena Weber
5/15/2009 07:23:10 AM
CSO

NDA REGULATORY FILING REVIEW
(Including Memo of Filing Meeting)

NDA # 22-024 Supplement # Efficacy Supplement Type SE-

Proprietary Name: ACTOPLUS MET XR
Established Name: pioglitazone + metformin extended-release (FDC)
Strengths: 15 mg/1000 mg; 30 mg/1000 mg.

Applicant: Takeda Global Research & Development Center, Inc.
Agent for Applicant: NA

Date of Application: April 30, 2008
Date of Receipt: May 1, 2008
Date clock started after UN:
Date of Filing Meeting: June 23, 2008
Filing Date: July 01, 2008
Action Goal Date (optional): User Fee Goal Date: **November 1, 2008**

Indication requested: This new drug application provides for the use of ACTOPLUS MET XR as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are already treated with pioglitazone and metformin or who have inadequate glycemic control on pioglitazone alone or metformin alone.

Type of Original NDA:	(b)(1) ☐	(b)(2) X
AND (if applicable)		
Type of Supplement:	(b)(1) ☐	(b)(2) ☐

NOTE:
(1) If you have questions about whether the application is a 505(b)(1) or 505(b)(2) application, see Appendix A. A supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2). If the application or efficacy supplement is a (b)(2), complete Appendix B.

Review Classification: Standard
Resubmission after withdrawal? NO Resubmission after refuse to file? NO
Chemical Classification: (1,2,3 etc.) 3
Other (orphan, OTC, etc.)

Form 3397 (User Fee Cover Sheet) submitted: YES

User Fee Status: Paid Exempt (orphan, government) ☐
Waived (e.g., small business, public health) ☐

NOTE: *If the NDA is a 505(b)(2) application, and the applicant did not pay a fee in reliance on the 505(b)(2) exemption (see box 7 on the User Fee Cover Sheet), confirm that a user fee is not required by contacting the User Fee staff in the Office of Regulatory Policy. The applicant is required to pay a user fee if: (1) the product described in the 505(b)(2) application is a new molecular entity or (2) the applicant claims a new indication for a use that that has not been approved under section 505(b). Examples of a new indication for a use include a new indication, a new dosing regime, a new patient population, and an Rx-to-OTC switch. The best way to determine if the applicant is claiming a new indication for a use is to compare the applicant's proposed labeling to labeling that has already been approved for the product described in the application.*

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