CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-073/S-014

Trade Name: Actos

Generic Name: (pioglitazone HCl)

Sponsor: Takeda Pharmaceuticals North America, Inc.

Approval Date: August 8, 2001

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APPLICATION NUMBER:

21-073/S-014

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APPLICATION NUMBER:

21-073/S-014

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-073/S-014

Takeda Pharmaceuticals, North America, Inc.
Attention: Robert M. Pilson, RRh
Manager, Regulatory Compliance
475 Half Day Road, Suite 500
Lincolnshire, IL 60059

Dear Mr. Pilson:

Please refer to your supplemental new drug application dated July 23, 2001, received July 24, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actos™ (pioglitazone hydrochloride) tablets, 15 mg, 30 mg, and 45 mg.

This supplemental new drug application provides for addition of [redacted] at [redacted] as a new packaging and labeling site for the drug product.

We have completed the review of this supplemental application, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Ms. Jena Weber, Regulatory Project Manager, at (301) 827-6422.

Sincerely,

{See appended electronic signature page}

Stephen K. Moore, Ph.D.
Chemistry Team Leader I, for
Division of Metabolic and Endocrine Drug Products,
(HFD-510)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Stephen Moore
8/3/01 05:52:37 PM

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APPLICATION NUMBER:

21-073/S-014

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW

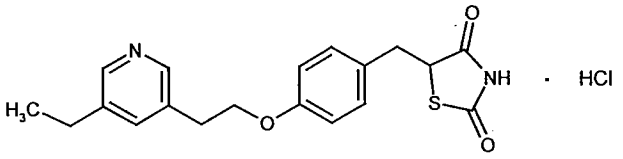
Organization CDER/HFD-510 Division of Metabolism and Endocrine Drug Products	**NDA # 21-073** Approved: 21-JUL-1999
Name and Address of Applicant: Takeda Pharmaceuticals North America, Inc. 475 Half Day Road, Suite 500 Lincolnshire, IL 60069 Phone: (847) 383-3023 Fax: (847) 383-3143	**Supplement** SCM-014 Doc. 23-JUL-2001 Rec. 24-JUL-2001 **Name Of The Drug** Actos™ Tablets **Nonproprietary Name** Pioglitazone Hydrochloride Tablets
Supplement provides for the addition of the [redacted] in [redacted] as a new packaging site for Actos™ Tablets.	**Amendment(s)** --

Pharmacological Category: Hypoglycemic Agent, treatment of NIDDM.	**How Dispensed** Oral Rx	**Supporting Documents** --
Dosage Form Tablets	**Potencies** 15-, 30- and 45-mg	

Chemical Name and Structure

Pioglitazone

$C_{19}H_{20}N_2O_3S \cdot HCl$
MW = 356.43 + 36.57 = 392.90



(±)-5[[4-[2-(5-ethyl-2-pyridinyl)ethoxy]phenyl]methyl]-2,4-thiazolidinedione monohydrochloride

Comments: This Supplement -Changes Being Effected in 30 days- provides for the addition of the [redacted] a new packaging site for the drug product, Actos™ Tablets. A request to the District Office for the evaluation [redacted] as initiated on August 1, 2001. **Acceptable cGMP status**, based on profile, was given on 02-AUG-2001 by the Office of Compliance (copy attached). Batches of Actos™ tablets packaged in [redacted] facility will be analyzed and tested by the methods approved in the NDA. The Applicant, **Takeda Pharmaceuticlas North America, Inc., commits to place samples of the first production batch of Actos™ tablets and at least one lot each year thereafter**, in each proposed commercial container/closure system in the Marketed Product Stability Testing Program using the approved protocol in the application. *Acceptable, regulatory requirements are fulfilled.*

Conclusions and Recommendations: [redacted] is acceptable for the packaging and labeling of the drug product Actos™ Tablets. From the CMC point of view, this supplement can be approved. **Issue Approval Letter.**

Reviewer Name (and signature) **Date Completed:** 02-AUG-2001

Xavier Ysern, PhD
Review Chemist

R/D Init.
Stephen Moore, PhD
Chemist Team Leader

filename: /nda/21073s14.doc

DISTRIBUTION: Original: NDA 21-073 cc: HFD-510 Division File/ WeberJ / MooreS/ YsernX

S-CBE 30 days
AP

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application: NDA 21073/014
Stamp: 24-JUL-2001
Regulatory Due: 24-JAN-2002
Applicant: TAKEDA PHARMS
475 HALF DAY RD STE 500
LINCOLNSHIRE, IL 60069
Priority: 1P
Org Code: 510

Action Goal:
District Goal: 20-DEC-2001
Brand Name: ACTOS (PIOGLITAZONE HCL) 15/30/45MG TABS
Estab. Name:
Generic Name: PIOGLITAZONE HCL

Dosage Form: (TABLET)
Strength: 15-, 30- AND 45-MG

Application Comment: NEW PACKAGING FACILITY MAY BE APPROVED BASED ON PROFILE (on 01-AUG-2001 by X. YSERN (HFD-510) 301-827-6420)

FDA Contacts: J. WEBER (HFD-510) 301-827-6422 , Project Manager
X. YSERN (HFD-510) 301-827-6420 , Review Chemist
S. MOORE (HFD-510) 301-827-6430 , Team Leader

Overall Recommendation: ACCEPTABLE on 02-AUG-2001 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: [redacted]

DMF No:

AADA:

Responsibilities: FINISHED DOSAGE LABELER
FINISHED DOSAGE PACKAGER

Profile: TCM

OAI Status: NONE

Estab. Comment: ADDITIONAL PACKAGING AND LABELING FACILITY MAY BE APPROVED BASED ON FILE PROFILED (on 01-AUG-2001 by X. YSERN (HFD-510) 301-827-6420)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	01-AUG-2001				YSERNX
OC RECOMMENDATION	02-AUG-2001			ACCEPTABLE BASED ON PROFILE	DAMBROGIOJ

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/s/

Xavier Ysern
8/2/01 10:26:17 AM
CHEMIST

AP

Stephen Moore
8/2/01 06:09:39 PM
CHEMIST