CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 21-073/S006

Trade Name: Actos

Generic Name: pioglitazone HCl

Sponsor: Takeda Pharmaceuticals Inc.

Approval Date: November 3, 2000

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APPLICATION NUMBER:
NDA 21-073/S006

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APPLICATION NUMBER:

NDA 21-073/S006

APPROVAL LETTER

NDA 21-073/S-006

Takeda Pharmaceuticals America, Inc.
Attention: Robert M. Pilson, R.Ph.
Manager, Regulatory Compliance
475 Half Day Road, Suite 500
Lincolnshire, IL 60069

Dear Mr. Pilson:

Please refer to your supplemental new drug application dated August 9, 2000, received August 10, 2000, 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.

We acknowledge receipt of your submission dated October 19, 2000.

This supplemental new drug application provides for the addition of , as a manufacture of the drug substance

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,

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

cc:
Archival NDA 21-073
HFD-510/Div. Files
HFD-510/XYsern/SMoore
HFD-511/JWeber
HFD-095/DDMS-IMT
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: jmw/October 18, 2000
Initialed by:XYsern 10/18/SMoore 11/1/EGalliers 11/2/00

final:JWeber 11/3/00
filename: N21073.006

APPROVAL (AP)

/s/

Jena Weber
11/3/00 10:30:19 AM

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APPLICATION NUMBER:

NDA 21-073/S006

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW

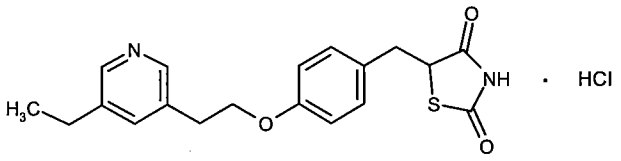
Organization CDER/HFD-510 Division of Metabolism and Endocrine Drug Products	**NDA # 21-073** Approved: 21-JUL-1999
Name and Address of Applicant: Takeda Pharmaceuticals America Inc. 101 Carnegie Center, Suite 207 Princeton, NJ 08540 Phone: (609) 452-1113 x-4409 Fax: (609) 452-1218	**Supplement** SCM-006 Doc. 09-AUG-2000 Rec. 10-AUG-2000 **Name Of The Drug** Actos™ Tablets **Nonproprietary Name** Pioglitazone Hydrochloride Tablets
Supplement provides for the addition of [redacted] as a manufacturer of the drug [redacted]	**New Correspondence** --

Pharmacological Category:	**How Dispensed**	**Supporting Documents**
Hypoglycemic Agent, treatment of NIDDM.	Oral Rx	--
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 [redacted], as a manufacturer of the drug substance [redacted] pyridyl)-ethoxy]benzylidene]-2,4-thiazolidinedione. Two manufacturers, Koei Chemical Co., Ltd. (Koei), and [redacted] The supplement provides information to assure that [redacted], manufactured by [redacted] has similar characteristics [redacted] manufactured by [redacted] Drug substance manufactured using [redacted] meet regulatory specifications and have similar properties than pioglitazone hydrochloride manufactured [redacted] *Adequate information has been provided, and all regulatory requirements have been fulfilled.*

Conclusions and Recommendations [redacted] has been found acceptable for the [redacted]/manufacture of the drug substance, Pioglitazone HCl. From the chemistry point of view, this supplement can be approved. **Issue approval letter.**

Reviewer Name (and signature) **Date Completed:** 17-OCT-2000

Xavier Ysern, PhD

R/D Init.

filename:

/nda/21073s06.doc

8 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 21-073 / 5006

/s/

Xavier Ysern
11/3/00 03:07:54 PM
CHEMIST

Steve Moore
11/3/00 05:45:28 PM
CHEMIST