

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 021073

CHEMISTRY REVIEW(S)

DIVISION OF METABOLISM AND ENDOCRINE DRUG PRODUCTS - HFD-510
Review of Chemistry, Manufacturing and Controls

NDA 21-073 Chemistry Review # 1 Date Reviewed: 24-JUN-1999

Submission Type	Document Date	CDER Rec. Date	Filing Date	U.F. ID #
Original	15-JAN-1999	15-JAN-1999	20-MAR-1999	3596
Amendment	11-JAN-1999			
Amendment	02-MAR-1999	03-MAR-1999		
Amendment	06-APR-1999	07-APR-1999		
Amendment	21-MAY-1999	24-MAY-1999		

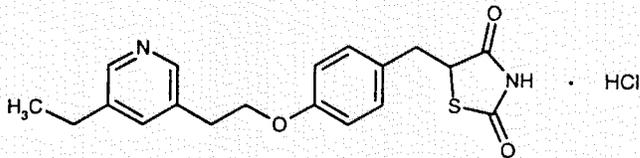
Applicant: Takeda America Research & Development
101 Carnegie Center, Suite 207
Princeton, NJ 08540
Phone: (609) 452-1113 x-4409
Fax: (609) 452-1218

Drug Product Name Proprietary: Actos™
 Nonproprietary/Established/USAN: Pioglitazone Hydrochloride
 Chem.Type/ Ther.Class: 1 S

Pharmacological Category/indication: Hypoglycemic Agent. Adjunct to diet to improve glycemic control in patients with NIDDM whose hyperglycemia cannot be managed by diet alone.

Dosage Form: Tablets **Strength(s):** 15-, 30- and 45-mg
Route of Administration: Oral **Dispensed:** R

Chemical Name, Structural Formula, Molecular Formula, Molecular Weight:



C₁₉H₂₀N₂O₃S · HCl
MW = 356.43 + 36.57 = 392.90
(±)-5[[4-[2-(5-ethyl-2-pyridinyl)ethoxy]phenyl]methyl]-2,4-thiazolidinedione monohydrochloride

Patent Information: Patent #/ Expiring date/ Type of patent/ Owner/
4,444,779/ 27-JUL-1999/ drug, thiazolidine derivatives/ Takeda Chemical Industries, Ltd./
4,687,777/ 17-JAN-2006/ thiazolidine derivatives, useful as antidiabetic agents/ Takeda Chemical Industries, Ltd./

Conclusions & Recommendations: Satisfactory CMC information has been provided for the drug substance, Pioglitazone HCl, and drug product, Actos™ (pioglitazone hydrochloride) Tablets. From the Chemistry viewpoint the application is approvable pending satisfactory results of the inspection of the manufacturing facilities and an acceptable response to the minor deficiencies listed in the Draft Letter. [REDACTED]

Orig. NDA 21-073
cc: HFD-510/Division File
HFD-510/SMalozowski/SMoore/RSteigerwalt/JWeber/XYsern
HFD-820/JGibbs

/S/ [REDACTED]

Xavier Ysern, PhD

R/D Init by:

AE
/S/ [REDACTED]

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