DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville MD 20857

NDA 21-073/S-010

Takeda Pharmaceuticals North America, Inc.
Attention: Janet L. Haskins
Regulatory Affairs Supervisor
475 Half Day Road, Suite 500
Lincolnshire, IL 6069

Dear Ms. Haskins:

Please refer to your supplemental new drug application dated March 2, 2001, received March 5, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actos (pioglitazone) Tablets.

We acknowledge receipt of your submissions dated January 11 and 22, and July 12, 2002(facsimile). Your submission of January 11, 2002 constituted a complete response to our January 4, 2002 action letter.

This supplemental new drug application provides for changes to the PRECAUTIONS section, Drug Interactions subsection. The pharmacokinetics of concomitant use of pioglitazone with the following compounds was added: fexofenadine, ranitidine, and nifedipine ER. The balance of the subsection was reworded to reduce redundancy.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the attached draft labeling.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-073/S-010." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Jena Weber, Regulatory Project Manager, at (301) 827-6422.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

David Orloff

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