DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-073/S-018

Takeda Pharmaceuticals North America, Inc.
Attention: Robert J. Pilson, R.Ph., J.D.
Manager, Regulatory Compliance
475 Half Day Road, Suite 500
Lincolnshire, IL 60059

Dear Mr. Pilson:

Please refer to your supplemental new drug application dated August 7, 2002, received August 8, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actos® (pioglitazone HCl) Tablets, 15 mg, 30 mg, and 45 mg.

This supplemental new drug application proposes to add a 7 count blister physician sample.

We completed our review of this supplemental new drug application. This supplement is approved.

The FPL for the carton and container labels must be identical to the submitted draft labeling.

Please submit copies of the FPL as soon as it is available. You may submit these labels electronically according to the guidance for industry titled, *Providing Regulatory Submissions in Electronic Format – NDA*.

We remind you that you must comply with the reporting requirements for an approved NDA (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}

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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