



JUL 29 2004

The Weinberg Group Inc.
Attention: Nicholas M. Fleischer, Ph.D.
1220 Nineteenth Street, NW, Suite 300
Washington, D.C. 20036-2400

Docket No. 02P-0499/CP1

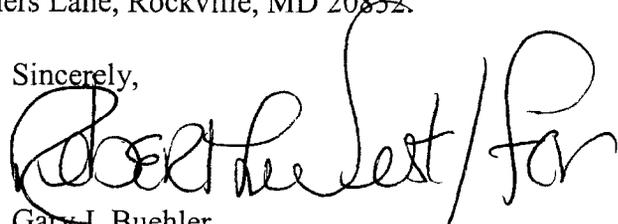
Dear Dr. Fleischer:

This letter is in reference to your petition approved on May 14, 2003, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Metformin Hydrochloride Tablets for Oral Solution, 500 mg, 850 mg, and 1000 mg. For your information, a waiver of the requirement for pediatric studies under PREA has been granted for these specific drug products. Therefore, the approval of your petition is reinstated.

On December 3, 2003, the "Pediatric Research Equity Act of 2003" (PREA) was signed into law. PREA requires that all applications for new active ingredients, new dosage forms, new indications, new routes of administration and new dosing regimens contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. PREA applies retroactively to applications submitted on or after April 1, 1999. Your petition is affected by this Act because it is an ANDA suitability petition that was approved for a change in dosage form and was submitted on or after April 1, 1999.

A copy of this letter will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,


Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

02P-0499

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