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OVERNIGHT COURIER

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Amendment to Citizen Petition
Docket Number 03P-0188/CP1
Inclusion of Pediatric Waiver Request**

Dear Sir or Madam:

The petition cited above was submitted on May 2, 2003. The petition requested the Commissioner of the Food and Drug Administration to declare that the drug product, Glyburide and Metformin Hydrochloride Tablets for Oral Solution, in strengths of 1.25 mg/250 mg; 2.5 mg/500 mg; and 5 mg/500 mg is suitable for submission in an abbreviated new drug application (ANDA).

In December of 2003, Congress passed the Pediatric Research Equity Act of 2003 that amended the Federal Food, Drug and Cosmetic Act to provide the Agency authority to require drug firms to study certain drugs in pediatric patients, if the Agency felt that such study would provide beneficial health data for that patient population. The act also provided a provision for a waiver from such requirement if:

- (iii) the drug or biological product;
- (I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and
- (II) is not likely to be used in a substantial number of pediatric patients.

The petitioner hereby requests that a waiver from the conduct of pediatric studies be granted for the approval of this petition to permit subsequent ANDA filing.

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The reference listed drug product is currently available in a conventional immediate-release tablet and is not, according to the approved labeling, recommended for use in pediatric patients. For this reason, the change in dosage form to a tablet for oral solution from an immediate-release tablet would not likely result in use in the pediatric population. In addition, the combination of Glyburide/Metformin does not appear on the historical listing of drug products for which studies may provide health benefits to the pediatric population. The proposed product, designed to provide a more convenient dosage form for adult patients that cannot swallow tablets, would therefore, not represent a meaningful benefit over existing therapies for the pediatric patient. In addition, based on the labeling of the proposed product it is not likely to be used in a substantial number of pediatric patients.

For the reasons stated above and consistent with the provisions of the Pediatric Research Equity Act of 2003, the petitioner respectfully requests that this waiver be granted.

Sincerely,



Nicholas M. Flesicher, R.Ph., Ph.D.
Vice President
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NMF/kh

cc Gary Buehler

