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CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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January 27, 2004

OVERNIGHT COURIER 1/27/04

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-0119/CP1
Inclusion of Pediatric Waiver Request**

Dear Sir or Madam:

The petition cited above was submitted on March 24, 2003. The petition requested the Commissioner of the Food and Drug Administration to declare that the drug product, Methadone Hydrochloride Tablets USP, 15 mg, 20 mg, 30 mg and 40 mg are suitable for consideration 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 patient be granted for the approval of this petition to permit subsequent ANDA filing.

The reference listed drug product is a dispersible tablet. This product is used for the detoxification treatment and maintenance therapy. The product is not indicated for the treatment of patients below the age of 18, unless under very specific circumstances, and then it may not be utilized in patients under the age of 16. The proposed product will contain the same warnings and recommendations of use.

Based on the use and nature of the RLD and the proposed product, the change in dosage form to an immediate-release tablet from a dispersible tablet would not likely change the use of the product or make it any more likely to be used in pediatric patients. In addition, the limitations of

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use and indications described in the labeling of the RLD make it unlikely that the proposed product would be used in a substantial number of pediatric patients. Also, it is noted that methadone did not appear on the historical listing of approved drug products for which additional pediatric information may produce health benefits in the pediatric population.

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. Due to the fact that the Agency has taken significantly longer than the 90-day period to respond to this ANDA suitability petition, the undersigned requests that the review of this waiver request be conducted in an expeditious manner.

Sincerely,



Robert W. Pollock
Vice President
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RWP/pk

cc: Emily Thomas (Office of Generic Drugs)
Martin Shimer (Office of Generic Drugs)

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