

**LACHMAN CONSULTANT SERVICES, INC.**  
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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2003P-0159 CP1 JAN 30 15 21E

January 29, 2004

**OVERNIGHT COURIER 1/29/04**

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 2003P-0159/CP1  
Inclusion of Pediatric Waiver Request**

Dear Sir or Madam:

The petition cited above was submitted on April 14, 2003. The petition requested the Commissioner of the Food and Drug Administration to declare that the drug products, Venlafaxine Hydrochloride Extended-Release Tablets, 37.5 mg (base), 75 mg (base) and 150 mg (base) are 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 patient be granted for the approval of this petition to permit subsequent ANDA filing.

The reference listed drug product is currently available in an extended-release tablet and appears not to be recommended for use in pediatric patients. The proposed product is an extended-release capsule. Venlafaxine has undergone pediatric studies as evidenced by the award of pediatric exclusivity to the innovator product. In this regard, it is not known whether a supplemental application for a labeling change has been submitted, and if so, whether it will be approved. However, since pediatric studies were conducted on this product, it would not seem reasonable to request that similar studies be repeated for a dosage form change thereby unnecessarily exposing children to the drug to prove what is already known. Should the

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innovator labeling change, the generic will be required to change its labeling to match the innovator unless the change is protected by patent or a period of market exclusivity. The ANDA applicant will be required to revise its labeling in accord with the regulations and the provisions of the Best Pharmaceuticals for Children Act. The introduction of a capsule dosage form of the product is not likely to provide a meaningful therapeutic benefit over existing therapies for pediatric patients nor would it be expected to diminish the knowledge gained by the conduct of pediatric studies already completed. For these reasons, the change in dosage form from an extended-release tablet to an extended-release capsule would not likely result in use in the pediatric population. 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,



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RWP/pk

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

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