

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

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January 9, 2004

**OVERNIGHT COURIER 1/9/04**

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-0091/CP1  
Inclusion of Pediatric Waiver Request**

Dear Sir or Madam:

The petition cited above was submitted on March 7, 2003. The petition requested the Commissioner of the Food and Drug Administration to declare that the drug product, Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Capsules (equivalent to 10 mg Hydrocodone Bitartrate and equivalent to 8 mg Chlorpheniramine Maleate) and Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Capsules (equivalent to 5 mg Hydrocodone Bitartrate and equivalent to 4 mg Chlorpheniramine Maleate) 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 liquid extended-release suspension product and is actually more suited for pediatric administration than the proposed extended-release capsules. In addition, the reference-listed drug, as explained in the body of the petition, is already labeled for dosing which includes dosing instructions for pediatric patients from age 6-12:

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Shake well before using.  
Adults: 1 teaspoonful (5 mL) every 12 hours;  
do not exceed 2 teaspoonfuls in 24 hours.

Children 6-12: 1/2 teaspoon every 12 hours;  
**do not exceed 1 teaspoonful in 24 hours.**

Not recommended for children under 6 years of age (see PRECAUTIONS).

The change in dosage form to an extended-release capsule from an extended-release suspension would actually make the product less attractive to pediatric patients younger than those for which the product is already labeled as safe and effective. Therefore, it is not likely that the proposed product would be used in a substantial number of pediatric patients for which the product is not already labeled. In addition, there are numerous approved liquid and solid oral dosage forms containing an antihistamine and cough suppressant that can be used in the place of the proposed product and, therefore, it would not represent a meaningful benefit over existing therapies for the pediatric patient.

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 *pk*

Vice President  
Lachman Consultant Services, Inc.  
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RWP/pk

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

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