



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305

Food and Drug Administration
Rockville MD 20857

JUL 30 2004

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Edward John Allera
Buchanan Ingersoll, P.C.
1776 K Street, NW
Suite 800
Washington, DC 20006

Re: Docket No. 2004P-0068/CP1

Dear Mr. Allera:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated February 2, 2004. Your petition requests that FDA establish specific bioequivalence requirements for oral products containing desmopressin. Specifically, you request that FDA require abbreviated new drug applications for these products to include the following:

- (1) Evidence from appropriate comparative clinical studies demonstrating bioequivalence to the reference listed drug (RLD) in terms of both pharmacokinetic and pharmacodynamic properties, including intrasubject as well as intersubject variability in absorption and duration of action as determined by measurement of urine osmolarity and flow rates in water loaded enuretic children,
- (2) Separate bioequivalence evidence for each dose level, and
- (3) If bioequivalence is not established by pharmacokinetic and pharmacodynamic studies, evidence from appropriate comparative clinical trials demonstrating efficacy and safety equivalent to the RLD in enuretic children.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0068

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