



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 28 2006

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Jorge Goldstein, Ph.D., Esq.
Brian J. Del Buono, Ph.D., Esq.
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1100 New York Avenue, NW
Washington, DC 20005

Re: Docket No. 2005P-0409/CP1

Dear Drs. Goldstein and Del Buono:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on October 5, 2005. Your petition requests that the Agency refrain from accepting the proposed trade name Patanase as part of a pending new drug application for olopatadine hydrochloride nasal spray.

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 possible given the numerous demands on the Agency's resources.

Sincerely,

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

2005P-0409

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