



DEPARTMENT OF HEALTH & HUMAN SERVICES

11-15-04

NOV 15 2004

Food and Drug Administration
Rockville MD 20857

C. Elaine Jones, Ph.D.
Vice President, US Regulatory Affairs
William M. Zoffer
Vice President, Assistant General Counsel
GlaxoSmithKline
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Re: Docket No. 2004P-0239/CP1

Dear Dr. Jones and Mr. Zoffer:

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 May 19, 2004. Your petition requests that the Agency expeditiously issue a final guidance document setting forth a scientifically valid methodology for determining bioequivalence (BE) for nasal spray products. It also requests that FDA refrain from approving any abbreviated new drug application for nasal suspension formulations, such as fluticasone propionate nasal spray, 50 mcg, until a final guidance has been established.

FDA has been unable to reach a decision on your petition because of 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,

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

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