



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 22 2004

Frederick H. Branding
Bell, Boyd & Lloyd, LLC
Three First National Plaza
70 West Madison Street, Suite 3300
Chicago, IL 60602-4207

Re: Docket No. 2004P-0206/CP1

Dear Mr. Branding:

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 3, 2004. Your petition requests that the Agency refrain from reviewing or approving any abbreviated new drug application for fluticasone propionate nasal spray, 50 mcg, unless it contains successful results of bioavailability and bioequivalence studies conducted under the methodologies set forth in FDA's April 2003 draft guidance entitled *Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action*.

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

2004P-0206

LET 2