DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 4 2006

Alan R. Bennett
Ropes & Gray, LLP
One Metro Center
700 12th Street, NW
Suite 900
Washington, DC 20005-3948

Re: Docket No. 2006P-0242/CP1

Dear Mr. Bennett:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on June 9, 2006, and submitted on behalf of AstraZeneca LP. Your petition requests that FDA publish a draft guidance on the demonstration of bioequivalence for locally acting oral inhalation suspension products and allow a period of public comment on the guidance before approving any abbreviated new drug application (ANDA) for a generic version of Pulmicort Respules (budesonide inhalation suspension). You also request that FDA (1) determine that labeling for a generic budesonide inhalation suspension product that omits once-daily dosing language would be legally impermissible, (2) require any ANDA applicant for a budesonide inhalation suspension product to conduct a clinical trial program as described in your petition to demonstrate bioequivalence to Pulmicort Respules, (3) consider whether it would be more appropriate to consider only applications described in section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act rather than ANDAs for approval of a generic budesonide inhalation suspension product, and (4) require any generic budesonide inhalation suspension product to meet certain product quality standards.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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 we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

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

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