



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

June 9, 2006

FILE COPY

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

Dear Mr. Bennett:

Your petition requesting the Food and Drug Administration to publish a draft guidance on demonstration of bioequivalence for locally acting oral inhalation suspension products and allow a period of public comment on that guidance before approving any follow-on budesonide inhalation suspension, was received by this office on 06/09/2006. It was assigned docket number 2006P-0242/CP 1 and it was filed on 06/09/2006. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega
Division of Dockets Management
Office of Management Programs
Office of Management

2006P-0242

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