



Food and Drug Administration
Rockville, MD 20857

May 18, 2004

C. Elaine Jones, Ph.D.
GlaxoSmithKline (GSK)
P.O. Box 13387
Research Triangle Park, North Carolina 27709
USA

Dear Dr. Jones:

Your petition requesting the Food and Drug Administration to Refrain from Approving any Further Abbreviated New Drug Applications (ANDAs) for Nasal Suspension Formulations, and Expediently Issue a Final and Complete Guidance Document to Determine Bioequivalence (BE) for Nasal Spray Products, was received by this office on 05/19/2004. It was assigned docket number 2004P-0239/CP 1 and it was filed on 05/19/2004. 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

