June 26, 2003

GlaxoSmithKline

Management Dockets, N/A
Dockets Management Branch
Food and Drug Administration
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Re: NAS 0; Not Product Specific
General Correspondence: Other
Comments on Draft Guidance for Industry: Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action (Second Draft, April 2003) [Docket No 99D-1738]

Dear Sir or Madam:

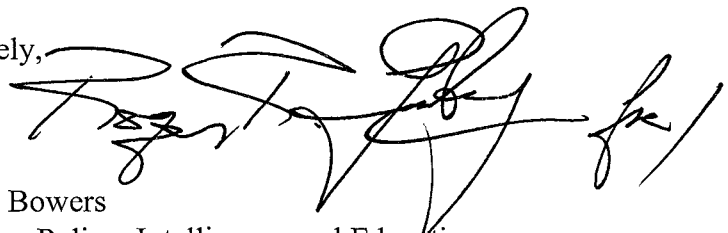
Please find enclosed comments from GlaxoSmithKline on the draft Guidance for Industry: **Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action**.

GlaxoSmithKline appreciates the opportunity to provide comments on this draft guideline. We agree with FDAs recognition of the challenges associated with assessing the bioavailability and bioequivalence of nasal sprays and nasal aerosols that exert their therapeutic effects via local action. Thus we support public definition of rigorous scientific standards against which interchangeability between Test and Reference products may be established. Our overall comments are followed by specific comments. Specific comments are organized under the same section headings as used in the draft guidance and cross-referenced by line number. All section headings are included.

This submission is provided in paper via duplicate copies with an additional copy on diskette (Word 97) and an electronic copy via email according to the instructions provided at http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm.

Please contact me at (919) 483-4483 if you require clarification of any of these comments. Thank you for your consideration.

Sincerely,



Alison Bowers
Director, Policy, Intelligence and Education
Regulatory Affairs