

June 27, 2005



GlaxoSmithKline

Management Dockets, N/A
Dockets Management Branch
Food and Drug Administration
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**Re: NAS 0; Not Product Specific
Response to FDA Request/Comment: Draft Guidance for Industry on Systemic Lupus
Erythematosus - Developing Drugs for Treatment [DOCKET NO. 2005D-0106]**

Dear Sir or Madam:

Enclosed please find comments from GlaxoSmithKline on the "Draft Guidance for Industry on Systemic Lupus Erythematosus - Developing Drugs for Treatment". We appreciate the need to clearly describe acceptable study endpoints to establish efficacy to facilitate the development of novel therapeutic agents which have the potential to be more effective and/or less toxic. We support the generation of this guidance for the development of therapies for the treatment of SLE. As this guidance follows on from a Concept Paper, entitled "Systemic Lupus Erythematosus" issued September 2003, overall we are in agreement with the present guidance. A specific comment is being provided, organized under the same section heading as used in the draft guidance and cross-referenced by line number.

This submission is provided in electronic format according to the instructions provided at <http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm?AGENCY=FDA>.

Please contact me at (919) 483-6405 if you require clarification or have questions about these comments. Thank you.

Sincerely,

A handwritten signature in black ink that reads "Anne N. Stokley".

Anne N. Stokley, M.S.P.H.
Director, Policy, Intelligence & Education
US Regulatory Affairs

**OVERALL COMMENTS ON DRAFT GUIDANCE FOR INDUSTRY:
SYSTEMIC LUPUS ERYTHEMATOSUS — DEVELOPING DRUGS
FOR TREATMENT**

**[DOCKET NO. 2005D-0106], MARCH 29, 2005 FEDERAL
REGISTER NOTICE**

We agree with FDA's statement as current therapies for SLE remain inadequate as many patients have incompletely controlled disease, progression to end-stage organ involvement continues, and current therapies carry potential risks of debilitating side effects. Therefore, it is important to clearly describe acceptable study endpoints to establish efficacy to facilitate the development of novel therapeutic agents which have the potential to be more effective and/or less toxic. Thus we support generation of this guidance for the development of therapies for the treatment of SLE. As this guidance follows on from a Concept Paper, entitled "Systemic Lupus Erythematosus" issued September 2003, overall we are in agreement with the present guidance.

These comments are being sent on behalf of GlaxoSmithKline. For questions or further information please contact Anne Stokley, Director, Policy, Intelligence and Education, US Regulatory Affairs, phone 919-483-6405.

**DETAILED COMMENTS, ANNOTATED BY SECTION OF THE
DRAFT GUIDANCE**

Section IV. SLE CLAIMS (line 264)

We would be interested to know if FDA would consider the ability to taper concomitant corticosteroids by clinically significant amounts as an acceptable outcome measure within section IV. A. "Reduction in Disease Activity of SLE". Although some of the disease activity scores used for SLE would capture additional treatments required for lupus, they would not specifically address reduction/withdrawal in corticosteroids. Tapering of corticosteroid use is included in this guidance document as an outcome measure in section IV. B. "Effectiveness in the Treatment of a Specific Organ System Manifestation" (line 296). We would like to understand why it was not included in Part A "The Reduction in Disease Activity of SLE" (line 264) of this section as well, since it may also be a measure of a reduction in disease activity.