



June 27, 2005

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2005D-0106: Comments on the draft Guidance for Industry - Systemic Lupus Erythematosus--Developing Drugs for Treatment

Dear Sir or Madam:

Hoffmann-La Roche, Inc. (Roche) is pleased to have an opportunity to provide comments on the draft Guidance for Industry - Systemic Lupus Erythematosus--Developing Drugs for Treatment (Docket No. 2005D-0106). The following comments are provided for consideration to enhance the clarity and application of this Guidance.

Section IV SLE claims, line 261

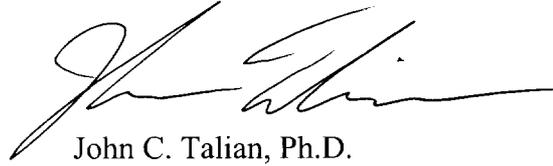
Comment: The agency provides a number of potential claims that require support by substantial evidence. Could the agency clarify if a reduction in disease activity or other endpoints require to be sustained and if so for how long in order to achieve a claim.

Section V Trial designs and analysis, lines 495 – 498

Comment: The agency suggests that an AUC analysis of disease activity may be used. Would the Agency clarify if any utility of AUC may be made for a primary endpoint and in what context an AUC analysis would be considered acceptable? For example, the BILAG itself covers disease activity over the previous month, and if this disease activity measure were applied for the duration of the study and an AUC applied to the BILAG would this be considered as a clinically valid interpretation of the efficacy response?

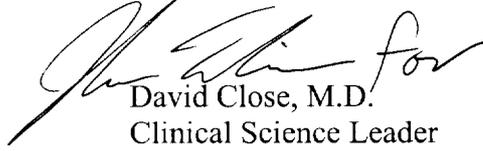
We appreciate the opportunity to present these comments and questions concerning this guidance. If you have any questions concerning the content of this response, please contact the undersigned.

Respectfully submitted,



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