

ASPREVA
PHARMACEUTICALS

26 June 2005

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

RE: Docket Number 2005D-0106, CDER 2004127

Dear Sir/Madam,

Aspreva Pharmaceuticals is an emerging pharmaceutical company focused on identifying, developing and commercializing new indications for approved drugs and drug candidates for underserved patient populations. Aspreva's "indication partnering" strategy allows its partners to maintain core brand focus while extending the benefits of their medicines to a broader patient population. Since 2003, the Company has been in collaboration with Hoffmann La Roche, Inc. to develop CellCept (mycophenolate mofetil) for various autoimmune indications, including lupus nephritis.

The Company is appreciative that FDA has prepared a draft guideline, "Guidance for Industry, Systemic Lupus Erythematosus – Developing Drugs for Treatment, March 2005". Aspreva believes that the Guidance, in its final form, will provide helpful insight to companies involved in the development of new therapeutics for this underserved area of medicine. Aspreva is in a unique position to comment on this document since the Company has recently launched a large and complex Phase III clinical trial with CellCept to treat lupus nephritis patients. This study will address treatment in the acute induction of remission stage, as well as the more long term maintenance phase. The program which will enrol 358 patients at over 100 sites around the world, will take 4-5 years to complete.

The challenges and alternatives faced by companies involved in developing clinical programs in SLE have been extensively documented in the Concept Paper for Systemic Lupus Erythematosus and the proceedings of the Advisory Committee meeting held in 2003. The draft Guidance continues that effort, but to be truly useful to industry, however, Aspreva recommends that the Guidance be more specific in capturing the Agency's thinking about the design of lupus studies that are ultimately approvable. The Guidance should lay out a clear road-map to regulatory approval for those involved with this area of clinical research. Unfortunately, while great effort has been expended to produce the current draft Guidance, this guideline more effectively documents the challenges already identified elsewhere rather than clearly stating what is required for regulatory approval.

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Specifically, Aspreva believes that clear and direct guidance in the following areas would be useful:

- Concurrence of comparable approaches across all Divisions of FDA dealing with lupus and its manifestations
- Statistical considerations in study design (non-inferiority vs. superiority)
- Identification of suitable surrogate endpoints
- Acceptability of potential accelerated approval pathways for therapies in this underserved area (Subpart H and Subpart E)

In the attached document, detailed comments have been provided. In each case, the section of the text from the draft Guidance has been reproduced, followed by the comment from Aspreva.

Aspreva welcomes the opportunity to comment on this draft Guideline and remains available to discuss the Company comments at FDA's convenience.

Sincerely,



Lawrence D. Mandt
Vice President
Regulatory Affairs