



June 27, 2005

Documents Management Division (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket Number 2005D-0106: Draft Guidance for Industry; Systemic Lupus Erythematosus- Developing Drugs for Treatment

For more than 25 years, Centocor has been a leader in the field of biomedicines. Through the dynamic science of biotechnology we continue to seek innovative ways to treat cancer, infectious diseases, cardiovascular and metabolic diseases, and immune-mediated inflammatory disorders (I.M.I.D.s), such as rheumatoid arthritis and psoriasis. Our work has revolutionized the science of immunology. We pioneered monoclonal antibody technology, a cutting-edge approach that launched a new generation of products to treat immune-related diseases.

As profound as these breakthroughs have been, they are just the beginning. Our ultimate goal is to develop cures for immune-related diseases. As such, we applaud the Agency's efforts to provide guidance to industry concerning the development of therapies for the treatment of Systemic Lupus Erythematosus (SLE). We found this to be a well-written and thoughtful document that provides substantive information pertaining to the clinical development of drugs for the treatment of SLE. Centocor has reviewed this draft guidance and respectfully wishes to provide the following specific comments:

Lines 385-388: *"Because of concerns that patients with an inactive urinary sediment may nonetheless progress to renal failure, we recommend that studies using renal remission as an outcome measure include follow-up renal biopsies in at least a subset of patients."*

Comment: Centocor agrees that follow-up renal biopsies in a subset of patients may provide additional confirmatory information as to the status of the disease. However, we anticipate that late phase development will include patients from outside of the US. We are concerned that Health Authorities outside of the US may question the acceptability of renal biopsy in these studies. Therefore, while this may be strived for in US development, global ethical issues may prevent this from occurring. We recommend that the guidance clarify this point.

Lines 722-724: *"It is important for the size of the safety database at approval be consistent with the recommendations made by the International Conference on Harmonisation (ICH guideline E1A)."*

Comment: Centocor agrees that for therapies intended to treat non-life-threatening aspects of SLE, it is appropriate for the size of the safety database to conform with the recommendations set forth in ICH E1A. However, for therapies intended to treat the life-threatening aspects of SLE, we would assert that the size of the safety database at approval need not necessarily conform with ICH E1A. Therefore we recommend that the guidance clarify this point.

Once again, Centocor appreciates the opportunity to provide comments regarding this draft guidance and would welcome a discussion with the Agency at any time.

Sincerely,

A handwritten signature in cursive script that reads "Kim Shields-Tuttle".

Kim Shields-Tuttle
Director
Worldwide Regulatory Affairs
Centocor, Inc.