

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0106]

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Draft Guidance for Industry on Systemic Lupus Erythematosus—Developing Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled “Systemic Lupus Erythematosus—Developing Drugs for Treatment.” The draft guidance is intended to provide recommendations for industry on developing drugs for the treatment of systemic lupus erythematosus (SLE). Specific topics include measurement of lupus disease activity and clinical outcomes, reduction in disease activity and flares, treatment of organ-specific disease, trial design issues and analysis, surrogate markers as endpoints, and risk-benefit assessment.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://cd04127>

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/www.fda.gov/dockets/ecomments. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Joel Schiffenbauer, Center for Drug Evaluation and Research (HFD-550),
Food and Drug Administration, 9201 Corporate Blvd., suite N316,
Rockville, MD 20850, 301-827-2090; or

Jeffrey N. Siegel, Center for Drug Evaluation and Research (HFD-108),
Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,
301-594-5667.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Systemic Lupus Erythematosus—Developing Drugs for Treatment.” SLE is a chronic disease characterized by protean manifestations often demonstrating a waxing and waning course. In the past, a diagnosis of SLE often implied a decreased life span due to internal organ system involvement or to toxic effects of therapy. However, recent improvements in care have dramatically enhanced the survival of SLE patients with the most severe and life-threatening manifestations. Unfortunately, current treatments for SLE remain inadequate as many patients have incompletely controlled the 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 endpoints for approval to facilitate the development of novel therapeutic agents which have the potential to be more effective and/or less toxic.

This draft guidance provides a general discussion of outcomes and measurements of lupus disease activity including the use of disease activity indices, flares, and organ-specific outcomes. It presents the indications that the agency may be willing to approve at present for new drug therapies for lupus. It also presents general trial design issues, discusses the use of surrogate endpoints in relation to lupus, presents the overall risk-benefit assessment that should be addressed for any new therapy of lupus, and presents some issues related to lupus and pharmacokinetics.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/ohrms/dockets/default.htm> or <http://www.fda.gov/cder/guidance/index.htm>.

Dated: 3/24/05
March 22, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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