

and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., rm. 374, Rockville, MD 20850, 240-276-0717.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled "Lupus Nephritis Caused By Systemic Lupus Erythematosus—Developing Medical Products for Treatment." This guidance is intended to assist sponsors in the clinical development of medical products for the treatment of LN caused by SLE. Specifically, the guidance addresses study population enrollment and efficacy endpoints for LN trials.

In the **Federal Register** of March 29, 2005 (70 FR 15868), FDA announced the availability of a draft guidance entitled "Systemic Lupus Erythematosus—Developing Drugs for Treatment," which included recommendations regarding medical product development for the treatment of LN caused by SLE. The recommendations specific to LN were removed from the draft guidance and are being finalized in this separate guidance. However, sponsors also should become familiar with the information regarding the overall development program and clinical trial designs for general SLE disease. The guidance entitled "Systemic Lupus Erythematosus—Developing Medical Products for Treatment," the availability of which is announced elsewhere in this issue of the **Federal Register**, provides general information on clinical trial considerations that may assist sponsors in studying LN, as well as providing specific information on trial design, trial duration, efficacy endpoints, and response criteria in SLE.

FDA received a number of comments on the draft guidance. The comments specific to LN were considered and incorporated, as appropriate, when finalizing this separate guidance. Other changes that were made include the addition of more specific examples of trial design and study endpoints, updating the science, and minor editorial changes to clarify specific issues. In addition, input was obtained from the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on developing medical products for the treatment of LN caused by SLE. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under OMB Control No. 0910-0014; the collections of information in 21 CFR part 314 have been approved under OMB Control No. 0910-0001; the collections of information in 21 CFR part 601 have been approved under OMB Control No. 0910-0338; and the collections of information in 21 CFR part 812 have been approved under OMB Control No. 0910-0078.

##### III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

##### IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>, or <http://www.regulations.gov>.

Dated: June 11, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-15081 Filed 6-21-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2005-D-0224] (formerly Docket No. 2005D-0106)

#### Guidance for Industry on Systemic Lupus Erythematosus—Developing Medical Products for Treatment; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Systemic Lupus Erythematosus—Developing Medical Products for Treatment." This guidance provides recommendations for industry on developing human drugs, therapeutic biological products, and medical devices for the treatment of systemic lupus erythematosus (SLE). This guidance finalizes the draft guidance entitled "Systemic Lupus Erythematosus—Developing Drugs for Treatment" (the draft guidance). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance entitled "Lupus Nephritis Caused by Systemic Lupus Erythematosus—Developing Medical Products for Treatment," which finalizes the parts of the draft guidance regarding lupus nephritis.

**DATES:** Submit either electronic or written comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448; or the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send one self-addressed adhesive label to assist the offices in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Jeffrey Siegel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3154, Silver Spring, MD 20993-0002, 301-796-2280; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210; or

Sahar M. Dawisha, Office of In Vitro Diagnostic Devices, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., rm. 374, Rockville, MD 20850, 240-276-0717.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled "Systemic Lupus Erythematosus—Developing Medical Products for Treatment." This guidance is intended to assist sponsors in the clinical development of medical products for the treatment of SLE. The guidance addresses the overall development program and clinical trial designs as well as specific information on claims, study design, study duration, efficacy endpoints, and response criteria.

In the **Federal Register** of March 29, 2005 (70 FR 15868), FDA announced the availability of a draft guidance entitled "Systemic Lupus Erythematosus—Developing Drugs for Treatment." FDA received a number of comments on the draft guidance, which were considered and incorporated, as appropriate, when finalizing the guidance. The recommendations regarding medical product development for lupus nephritis were removed from this guidance and placed into a separate guidance, the availability of which is announced elsewhere in this issue of the **Federal Register**. Additional organ-specific guidances will be developed in the future. Other changes that were made include the addition of more specific examples of trial design and study endpoints, updating the science, and minor editorial changes to clarify specific issues. In addition, input was obtained from the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health.

This guidance is being issued consistent with FDA's good guidance

practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on developing medical products for the treatment of SLE. 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. The Paperwork Reduction Act of 1995**

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Dated: June 11, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-N-2010-0001]

**Blood Products Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Blood Products Advisory Committee.

*General Function of the Committee:*

To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on July 26, 2010, from 8 a.m. to approximately 5:30 p.m. and July 27, 2010, from 8 a.m. to approximately 1 p.m.

*Location:* Hilton Washington DC/North, 620 Perry Pkwy., Gaithersburg, MD.

*Contact Person:* Bryan Emery or Pearlina Muckelvene, Center for Biologics and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On July 26, 2010, in the morning session, the committee will hear updates on the following topics: June 10 and 11, 2010, meeting of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability; December 14 and 15, 2009, FDA workshop on emerging arboviruses; May 11 and 12, 2010, FDA workshop on emerging infectious diseases; and the Q fever epidemic in the Netherlands. The committee will also hear informational presentations on Xenotropic Murine Leukemia Virus-Related Virus. In the