

What to submit	Where found	When to submit
Project Sustainability Plan .....	Referenced in Section IV.2 of the announcement under "Project Description".	Required of all applicants for projects of three years (36 months) or more in length. By application due date found in Overview and Section IV.3.
Certification Regarding Lobbying .....	Referenced in Section IV.2 of the announcement and found at <a href="http://www.acf.hhs.gov/grants/grants_resources.html">http://www.acf.hhs.gov/grants/grants_resources.html</a> .	Submission due by date of award.
This program is covered under E.O. 12372, "Intergovernmental Review of Federal Programs," and 45 CFR Part 100, "Intergovernmental Review of Department of Health and Human Services Programs and Activities". Applicants must submit all required application materials to the State Single Point of Contact (SPOC) and indicate the date of submission on the Standard Form (SF) 424 at item 19.	Applicants should go to the following URL for the official list of the jurisdictions that have elected to participate in E.O. 12372, <a href="http://www.whitehouse.gov/omb/grants_spoc/">http://www.whitehouse.gov/omb/grants_spoc/</a> as indicated in Section IV.4 of this announcement.	Submission due to State Single Point of Contact by the application due date found in Overview and Section IV.3.
Logic Model .....	Referenced in Section IV.2 of the announcement under "Project Description".	Submission due by application due date found in Overview and Section IV.3.
SF—LLL—Disclosure of Lobbying Activities, if applicable.	"Disclosure Form To Report Lobbying" is referenced in Section IV.2 and found at <a href="http://www.acf.hhs.gov/grants/grants_resources.html">http://www.acf.hhs.gov/grants/grants_resources.html</a> . Submission of this form is required if any funds have been paid, or will be paid, to any person for influencing, or attempting to influence, an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States to insure or guarantee a loan.	Submission due by application due date found in Overview and Section IV.3.

*Contact for Further Information:*  
Marnay Cameron, Program Specialist,  
Family and Youth Services Bureau, 370  
L'Enfant Promenade, SW., Washington,  
DC 20447. Telephone: 202-205-8657, e-  
mail: [Marnay.cameron@acf.hhs.gov](mailto:Marnay.cameron@acf.hhs.gov).

Dated: June 10, 2010.

**Bryan Samuels,**

*Commissioner, Administration on Children,  
Youth and Families.*

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**BILLING CODE 4182-03-P**

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-D-0249]

**Guidance for Industry on Lupus  
Nephritis Caused By 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 "Lupus Nephritis Caused By  
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 lupus  
nephritis (LN) caused by systemic lupus  
erythematosus (SLE). This guidance  
finalizes the parts of the draft guidance  
entitled "Systemic Lupus  
Erythematosus—Developing Drugs for  
Treatment" (the draft guidance)  
regarding LN. Elsewhere in this issue of  
the **Federal Register**, FDA is  
announcing the availability of the  
guidance entitled "Systemic Lupus  
Erythematosus—Developing Medical  
Products for Treatment," which finalizes  
the draft guidance. Additional organ-  
specific guidances will be developed in  
the future.

**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 "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.*

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## 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.