DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0106]

Draft Guidance for Industry on Systemic Lupus Erythematosus—Developing Drugs for Treatment; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Systemic Lupus Erythematosus—Developing Drugs for Treatment.'' The draft guidance is intended to provide recommendations for industry on developing drugs for the treatment of systemic lupus erythematosus (SLE).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DATES: Submit written or electronic comments on the draft guidance by June 27, 2005. 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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://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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled ''Systemic Lupus Erythematosus—Developing Drugs for Treatment.''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: March 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6085 Filed 3–28–05; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Cancellation of Customs Broker License Due to Death of the License Holder

AGENCY: Bureau of Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: Notice is hereby given that, pursuant to Title 19 of the Code of Federal Regulations § 111.51(a), the following individual Customs broker licenses and any and all permits have been cancelled due to the death of the broker:

Name	License No.	Port name
Enoch Van Hoesen	2528	New York.
Manuel A. Gonzalez	05742	Miami.
Sherry A. Ireland	22657	Detroit.
Joan P. Shindledecker	9808	Baltimore.
Robert E. Finley, Sr.	3448	Mobile.
Gabe S. Fountain	9170	Mobile.

Dated: March 18, 2005.

William S. Heffelfinger III,

Acting Assistant Commissioner, Office of Field Operations.

[FR Doc. 05–6105 Filed 3–28–05; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Notice of Cancellation of Customs Broker Permit

AGENCY: Bureau of Customs and Border Protection, U.S. Department of Homeland Security.

ACTION: General Notice.

SUMMARY: Pursuant to section 641 of the Tariff Act of 1930, as amended, (19 U.S.C. 1641) and the Customs Regulations (19 CFR 111.51), the following Customs broker local permits are canceled without prejudice.

Name	Permit No.	Issuing port
Godwin Shipping Company, Inc	19–03–H39	Mobile.
Kamino International Transport, Inc	00–014	Houston.
Steven Hsien-Lin Wang dba WHL Customs Broker Services	200108	Los Angeles.
Dynamic Ocean Services International, Inc	94–2101–1	Houston.
James P. Cesped	26–02–WSK	Nogales.
Marvin Madden	19–03–J20	Mobile.
David Meth	DF5	Miami.
Robert Conyers	52–03–AUR	Miami.

Dated: March 18, 2005.

William S. Heffelfinger III,

Acting Assistant Commissioner, Office of Field Operations.

[FR Doc. 05–6104 Filed 3–28–05; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF THE INTERIOR

Indian Arts and Craft Board

Proposed Renewal of Information Collection for Source Directory Publication; Comment Request

AGENCY: Indian Arts and Crafts Board, Interior.

ACTION: Notice.

SUMMARY: The Indian Arts and Crafts Board collects information to identify and revise listings for the Source Directory of American Indian and Alaska native owned and operated arts and crafts businesses. Comments on renewal of this collection are requested from the public. After the public review, we will submit the information collection to OMB–OIRA for review and re-approval as required by the Paperwork Reduction Act of 1995.

DATES: Submit comments on or before May 3, 2005.

ADDRESSES: Send your written comments to Attention: Indian Arts and Crafts Board, U.S. Department of the Interior, 1849 C Street, NW., MS–2058 MIB, Washington, DC 20240. If you wish to submit comments by facsimile, the number is (202) 208–5196, or you may send them by e-mail to ''*iacb@ios.doi.gov.*'' Please mention that your comments concern the Source Directory.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the Source Directory application or renewal forms, *i.e.,* the information collection instruments, should be directed to Meridith Z. Stanton, Director, Indian Arts and Crafts Board, 1849 C Street, NW., MS 2058 MIB, Washington, DC 20240. You may also call (202) 208–3773 (not a toll free call), or send you request by e-mail to ''*iacb@ios.doi.gov*'' or by facsimile to (202) 208–5196.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Source Directory of American Indian and Alaska Native owned and operated arts and craft enterprises is a program of the Indian Arts and Crafts Board that promotes American Indian and Alaska Native arts and crafts. The Source Directory is a forty-one page full-color illustrated publication featuring fine examples of contemporary American Indian and Alaska Native art from the major cultural areas in the United States. The Source Directory also comes with a listing of American Indian and Alaska native owned and operated arts and crafts businesses. This listing is included as an insert in the back cover of the Source Directory.

The service of being listed in this publication is provided free-of-charge to members of federally recognized tribes. Businesses listed in the Source Directory include American Indian and Alaska Native artists and craftspeople, cooperatives, tribal arts and crafts enterprises, businesses privately-owned-and-operated by American Indian and Alaska native artists, designers, and craftspeople, and businesses privately owned-and-operated by American Indian and Alaska Native merchants who retail and/or wholesale authentic Indian and Alaska native arts and crafts. Business listings in the Source Directory are arranged alphabetically by State. The Source Directory may be ordered from either the Oklahoma Arts and Crafts Cooperative, P.O. Box 966, Anadarko, Oklahoma 73005 or the Sioux Indian Museum, 222 New York Street, Rapid City, South Dakota 57701, for a cost of $11.50 which includes shipping and handling. The business listings are also available on the Board's Web site located at *http://www.iacb.doi.gov.*

The Director of the Board uses this information to determine whether an individual or business applying to be listed in the Source Directory meets the requirements for listing. The approved application will be printed in the Source Directory. The Source Directory is updated annually to include new businesses and to update existing information.

II. Method of Collection

To be listed in the Source Directory, interested individuals and businesses must submit: (1) A letter requesting an entry in the Source Directory, (2) a draft of their business information in a format like the other Source Directory listings, (3) a copy of the individual's or business owner's tribal enrollment card; and for businesses, proof that the business is organized under tribal, state, or federal law; and (4) a certification that the business is an American Indian or Alaska Native owned and operated cooperative, tribal enterprise, or nonprofit organization, or that the owner of the enterprise is an enrolled member of a federally recognized