DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 04097]

Role of the Environment in the Transmission of SARS Co-v; Notice of Intent To Fund Single Eligibility Award

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2004 funds for a cooperative agreement program to address several outstanding questions regarding the role of the environment in SARS transmission and to provide important information about pathogen transmission in isolation facilities, appropriate cleaning procedures, and appropriate procedures for donning/removal of personal protective equipment. The Catalog of Federal Domestic Assistance number for this program is 93.283.

B. Eligible Applicant

Assistance will be provided only to the University of North Carolina.

• Experience of UNC Staff

It is in the best interest of CDC to utilize the expertise of Drs. Sobsey, Weber and Rutala from the University of North Carolina, who have combined, over 80 years of experience in microbial inactivation studies using a wide range of microorganisms, including a wide range of viruses.

The UNC BSL3 laboratory is shared with Dr. Ralph Baric, who has spent the last twenty years studying how coronaviruses are transmitted among species. Dr. Baric currently has research support form the National Institutes of Health for a variety of research projects involving SARS. Thus, UNC has the unique opportunity to collaborate with Dr. Baric, one of the world's experts in coronaviruses.

Lastly, UNC has a cadre of researchers that are well trained in microbial inactivation studies and have published several hundred papers on this subject.

• Urgency of the Need to Address the SARS Co-v Research Questions

The emergence of severe acute respiratory syndrome (SARS) produced an international health emergency in the late winter and into early spring in 2003. By early July there were an estimated 8,439 probable cases and 812 deaths from severe acute respiratory syndrome (SARS) identified from 30 countries (URL: *http://www.who.int/csr/sars/en/*). A newly described coronavirus SARS-CoV was implicated. SARS outbreaks were reported in China (Beijing, Guandong, and Hong Kong), Vietnam (Hanoi), Singapore, Taiwan, and Canada (Toronto). During the outbreak SARS-CoV was being transmitted both in the community and in the healthcare facilities.

• Immediate Availability of BSL3 Laboratory

The University of North Carolina BSL3 laboratory is now available to conduct the research. This will enable a timely response to research questions regarding how long infectious virus can persist on common hospital environmental surfaces, wastewater, etc., or the role of personal protective equipment for protecting health-care workers. While other institutions may have BSL3 capability, the facilities are usually restricted to use with a limited number of infectious agents. For example, a facility conducting work on Mycobacterium tuberculosis would not use the same BSL3 facility for working with coronaviruses, since disinfection schemes would be different, and the necessity for cell culture materials and unique pieces of equipment would likely require remodeling. A facility such as that at UNC that is already equipped to work with coronoaviruses saves considerable expense in retooling a BSL3 to work with this virus.

C. Funding

Approximately $500,000 is available in FY 2004 to fund this award. It is expected that the award will begin on or before July, 2004, and will be made for a 18 month budget period within a project period of up to 18 months. Funding estimates may change.

D. Where To Obtain Additional Information

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For technical questions about this program, contact: Matthew Arduino, Dr.P.H., Extramural Project Officer, Division of Healthcare Quality Promotion, Epidemiology and Laboratory Branch, NCID, 1600 Clifton Road, NE. Building 17, Room 4211 C–16, Telephone: (404) 639–2318, E-mail: *MAarduino@cdc.gov.*

Dated: June 3, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0509]

International Conference on Harmonisation; Guidance on the M4 Common Technical Document—Quality: Questions and Answers/Location Issues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''M4: The CTD—Quality: Questions and Answers/Location Issues.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This guidance provides further clarification for preparing the quality components of an application file in the common technical document (CTD) format. The guidance addresses the relationship between linked sections for certain parameters (such as polymorphism and particle size), and it addresses location issues (by indicating the section in which to place requested information). The guidance is intended to ease the preparation of paper and electronic submissions, facilitate regulatory reviews, and simplify the exchange of regulatory information among regulatory authorities.

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written comments on the 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.* Submit written requests for single copies of the 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, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing

your requests. Requests and comments should be identified with the docket number found in brackets in the heading of the document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Justina A. Molzon, Center for Drug Evaluation and Research (HFD–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400; or Christopher C. Joneckis, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0833.

Regarding the ICH: C. Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0908.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health, Labour, and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of October 16, 2001 (66 FR 52634), FDA made available the ICH guidance entitled ''M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use'' (M4 CTD), which describes a harmonized format for new product applications (including applications for biotechnology-derived products) for submission to the regulatory authorities in the three ICH regions. The M4 CTD guidance was made available in four parts: (1) A description of the organization of the M4 CTD; (2) the quality section; (3) the safety, or nonclinical, section; and (4) the efficacy, or clinical, section.

In the **Federal Register** of December 30, 2002 (67 FR 79639), FDA published a notice announcing the availability of a draft tripartite guidance entitled ''Common Technical Document—Quality: Questions and Answers/Location Issues.'' The notice gave interested persons an opportunity to submit comments by February 28, 2003. After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in July 2003.

This guidance provides further clarification for preparing the quality components of an application in the CTD–Q format. The guidance addresses the relationship between linked sections for certain parameters, such as polymorphism and particle size. The guidance also addresses location issues by indicating the section in which to place requested information. The guidance is intended to ease the preparation of paper and electronic submissions, facilitate regulatory reviews, and simplify the exchange of regulatory information among regulatory authorities.

This guidance represents 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 guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The 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/cder/guidance/index.htm*, *http://www.fda.gov/cber/publications.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: June 3, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000D–1392]

Guidance for Industry on Botanical Drug Products; 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 ''Botanical Drug Products.'' FDA has revised a draft guidance issued on August 11, 2000, in response to comments from industry and other interested persons. The guidance explains the circumstances under which FDA regulations require approval of a new drug application (NDA) for marketing of a botanical drug product and when such a product may be marketed under an over-the-counter (OTC) drug monograph. It also provides guidance to sponsors on submitting investigational new drug applications (INDs) for botanical drug products.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–