No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by FDA (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). No burden has been estimated for Forms FDA 1994 and 1995 because they are not currently being used. The Secretary of Health and Human Services has the discretion to allow Form FDA 1815, a duly certified statement signed by an accredited official of a foreign Government, to be submitted in lieu of Forms FDA 1994 and 1995. To date, Form FDA 1815 has been submitted in lieu of these forms.

Dated: July 19, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–18927 Filed 7–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement to Support the Joint Institute for Food Safety and Applied Nutrition; Notice of Intent to Supplement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to noncompetitively supplement the cooperative agreement with the University of Maryland, College Park (UMCP) for up to an estimated $2 million per annum. These funds will provide additional support to the UMCP's Joint Institute for Food Safety and Applied Nutrition (JIFSAN) for the purpose of addressing emerging health issues and crises that are related to food safety and applied nutrition and animal health sciences, and expanding the current scope to include other agency programs such as cosmetics.

DATES: Submit the application by August 25, 1999. If this date falls on a weekend, it will be extended to Monday; if this date falls on a holiday, it will be extended to the following workday.

ADDRESSES: An application is available from and should be submitted to: Maura C. Stephanos, Office of Regulatory Affairs Support and Assistance Management Branch (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7183. If the application is hand carried or commercially delivered, it should be addressed to Maura C. Stephanos, 5630 Fishers Lane, rm. 2129, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Maura C. Stephanos (address above).

Regarding the programmatic aspects: Elizabeth M. Calvey, Center for Food Safety and Applied Nutrition (HFS–6), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4716.

SUPPLEMENTARY INFORMATION: This project is authorized under section 301 of the Public Health Service Act (the PHS Act) (42 U.S.C. 241). This activity is generally described in the Catalog of Federal Domestic Assistance at No. 93.103. The application will not be subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Program (45 CFR part 100).

I. Restricted Eligibility

In the **Federal Register** of May 22, 1997 (62 FR 28049), FDA announced that a single source application for a cooperative agreement to support the JIFSAN at the UMCP would be accepted. Supplemental funding referenced herein will provide for the implementation and enhancement of activities associated with the JIFSAN projects described and authorized under the original award (FD–U–001418–01) dated September 29, 1997.

II. Availability of Funds

FDA will provide supplemental funding up to an estimated $2 million per annum to the cooperative agreement, which is at a level greater than the 25 percent of the original award currently provided under agency policy. Supplemental funding will provide support of the JIFSAN programs primarily through available Food Safety Initiative funds and funds from other government agencies.

The original cooperative agreement was approved for 5 years of funding and currently has 3 years of noncompetitive support remaining, which is contingent upon the availability of fiscal year appropriations and successful performance. FDA anticipates that supplemental funding of the cooperative agreement will commence on or before September 30, 1999.

III. Background

JIFSAN was established between FDA and the UMCP in April 1996, through a formal Memorandum of Understanding (MOU), to create a partnership that allows for more efficient use of research resources, thereby enhancing overall public health by expanding and improving food safety and nutrition research as well as research in other program areas that impact on public health policy. As the role of FDA research scientists in regulatory activities increases (e.g., petition review, rulemaking, enforcement compliance standards, hazard analysis critical control point performance standards), it is vital that these same scientists have ready access to very specialized research facilities and expertise that are in close proximity to FDA's administrative offices. The unique needs for research in support of regulatory programs has been one of the key reasons for maintaining a strong FDA research program. JIFSAN is a jointly administered, multi-disciplinary research and outreach program. JIFSAN was established as part of FDA's consolidation project affecting FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine. The primary focus of JIFSAN is food safety and nutrition, specifically as related to risk analysis, applied microbiology, natural toxins, chemical contaminants, animal health sciences, and food composition and nutrition. JIFSAN also encompasses other agency programs such as cosmetics, dietary supplements, and food labeling.

IV. Purpose

Supplemental funding to FDA's current cooperative agreement will provide the UMCP with the necessary resources to conduct further research related to the goals of the National Food Safety Initiative and to leverage additional resources for applied nutrition, animal health science activities, and other agency programs. These resources would: (1) Expand the expertise for public health research and risk assessment initiatives, (2) support the Risk Assessment Consortium, and (3) increase innovative public/private research and education partnerships. Because international safety regulations must be founded on science-based risk assessments, FDA's scientists must have a lead role in their development.

Additionally, supplemental funding will provide resources to identify gaps in risk analysis to: (1) Minimize/reduce uncertainty in risk management decisions; (2) improve the quality of risk assessments applied to agency

programs, principally but not limited to food safety and applied nutrition (e.g., microbial pathogens, natural toxins, chemical contaminants, and food composition and nutrition); and (3) enhance risk communication, through outreach and public information programs, that will help the mass media and consumers understand and act on public health concerns. Innovative research and outreach efforts, made possible by the supplemental funding, will complement existing efforts under FDA's current cooperative agreement with the UMCP and will provide public health officials with the appropriate knowledge to formulate regulatory decisions and enhanced capabilities to communicate with their stakeholders.

V. Substantive Involvement by FDA

All terms and conditions of the current award shall remain in full force and effect for the supplemental awards.

VI. Review Procedure

The application submitted by the UMCP will undergo a noncompetitive, dual peer review. The application will be reviewed for scientific and technical merit by a panel of experts based on applicable evaluation criteria. If the application is recommended for approval it will then be presented to the National Advisory Environmental Health Sciences Council.

VII. Reporting Requirement

All terms and conditions of the current award shall remain in full force and effect for the supplemental awards.

VIII. Mechanism of Support

Support will be in the form of supplements to FDA's cooperative agreement with the UMCP. This agreement will be subject to all policies and requirements that govern the research grant program of the Public Health Service, including provisions of 42 CFR part 52 and 45 CFR part 74.

Dated: July 15, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–18929 Filed 7–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2096]

Draft ''Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations.'' The draft guidance document is intended to provide sponsors and manufacturers FDA's current thinking on the criteria by which two monoclonal antibody products would be considered the same under the Orphan Drug Act and implementing regulations.

DATES: Written comments may be submitted at any time, however, comments should be submitted by October 25, 1999, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–940), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance. Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations.''

In the **Federal Register** of December 29, 1992 (57 FR 62076), FDA published the orphan drug regulations final rule. The final rule established in part 316 (21 CFR part 316) regulations that prescribe certain incentives for the development of ''orphan drugs,'' drugs which are intended for use in rare diseases or conditions. One of the incentives for orphan drug development is to obtain exclusive approval for the pioneer product for a period of 7 years during which no approval will be given to a subsequent sponsor of the same drug product for the same indication unless it proves to be clinically superior, as defined in § 316.3(b)(3). In determining whether or not two products would be considered the same, FDA recognized that different criteria were necessary for macromolecules versus small molecules (§ 316.3(b)(13)). Macromolecules include a variety of structures including proteins, nucleic acids, carbohydrates and closely related, complex, partly definable drugs such as vaccines or surfactants. The current definition of sameness for protein drugs (§ 316.3(b)(13)(ii)(A)) however, does not consider the unique nature of antibodies. The draft document is intended to describe FDA's thinking on the criteria by which two monoclonal antibody products would be considered the same under the Orphan Drug Act and its implementing regulations.

This draft guidance document represents the agency's current thinking on the interpretation of the orphan drug regulations as they pertain to monoclonal antibodies. 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 requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written