information collection and has assigned OMB control number 0910–0330. The approval expires on July 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at ''http://www.fda.gov/ohrms/dockets''.

Dated: July 15, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–18696 Filed 7–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement to Support a National Center for Food Safety and Technology; Notice of Intent to Renew a Cooperative Agreement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to accept and consider a single source application for the award of a cooperative agreement in fiscal year 1999. An estimated amount of $2 million per year, with an additional 4 years of support, is available to the Illinois Institute of Technology (IIT) to support the National Center for Food Safety and Technology (NCFST), which is located on IIT's Moffett Campus in Summit-Argo, IL. Competition is limited to IIT because IIT has the unique capability to bring together diverse perspectives on food safety; IIT has access to the exceptional combination of scientific expertise, pilot plants, and research facilities necessary to focus those perspectives on cooperative food safety programs; and IIT has underway a cooperative food safety research program and an academic degree program in food safety. This is the first American effort to join the resources of government, academia, and industry in a consortium to study issues of food safety.

DATES: Submit applications by August 23, 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 (address below). Applications hand carried or commercially delivered should be addressed to Maura C. Stephanos, 5630 Fishers Lane, rm. 2129, Rockville, MD 20852, FAX 301–827–7106, e-mail address: mstepha1@oc.fda.gov.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice contact: Maura C. Stephanos, Senior Grants Management Specialist, Office of Regulatory Affairs Support and Assistance Management Branch (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7183.

Regarding the programmatic aspects contact: Karen L. Carson, Center for Food Safety and Applied Nutrition (HFS–22), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5140, FAX 202–205–4525, e-mail address: kcarson@bangate.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing its intention to accept and consider a single source application from IIT for a cooperative agreement to support the NCFST. FDA's authority to enter into grants and cooperative agreements is set out in section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance No. 93.103. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public.

IIT's application for this award will undergo dual peer review. An external review committee of experts in food science research will review and evaluate the application based on its scientific merit. A second level review will be conducted by the National Advisory Environmental Health Science Council.

I. Background

In the **Federal Register** of May 3, 1988 (53 FR 15736), FDA published a request for applications for a cooperative agreement to establish a National Center for Food Safety which would join the resources of government, academia, and industry in a consortium to study questions of food safety. FDA awarded the cooperative agreement to IIT in September 1988. Applications received were competitively reviewed by a panel of non-FDA food scientists, and the award approved by the National Advisory Environmental Health Science Council in September 1988.

In the **Federal Register** of September 10, 1991 (56 FR 46189) and in the **Federal Register** of May 12, 1994 (59 FR 24703), FDA published notice of its intention to limit consideration for the award of a cooperative agreement to IIT to support the NCFST. FDA awarded the cooperative agreement to IIT on September 30, 1991, and September 26, 1994, respectively, following competitive review of the application by a panel of non-FDA food scientists. The award was approved by the National Advisory Environmental Health Science Council in September 1991 and in September 1994, respectively.

Under the cooperative agreement, IIT has established and staffed the NCFST at IIT's Moffett Campus in Summit-Argo, IL. Other participants in this effort are the IIT Research Institute; the Food Science Department of the University of Illinois, Urbana-Champaign; FDA; and industry. The NCFST is structured so that representatives of participating organizations play a role in establishing policy and administrative procedures, as well as identifying long- and short-term research needs. With this organizational structure, the NCFST is able to build cooperative food safety programs on a foundation of knowledge about current industrial trends in food processing and packaging technologies, regulatory perspectives from public health organizations, and fundamental scientific expertise from academia. The structure and programs at the NCFST positioned the Center as a focal point of FDA's participation in research and risk assessment associated with the President's Food Safety Initiative (FSI). Specifically, the work at NCFST focuses on development of preventive technologies targeted to reduce or eliminate microbial contamination of foods that results in foodborne illness. The work at the NCFST complements and feeds into FSI risk assessment and other activities at the Joint Institute for Food Safety and Applied Nutrition at the University of Maryland.

II. Mechanism of Support

A. Award Instrument

Support for this program, if granted, will be in the form of a cooperative agreement. In 1999, FDA is providing $2 million for this award. The award will be subject to all policies and requirements that govern the research grant programs of the Public Health Service (PHS), including the provisions of 42 CFR part 52, 45 CFR part 74, and the PHS Grants Policy Statement.

B. Length of Support

The length of support will be 1 year with the possibility of an additional 4 years of noncompetitive support. Continuation, beyond the first year, will be based upon performance during the preceding year and the availability of Federal fiscal year appropriations.

III. Reasons for Single Source Selection

FDA believes that there is compelling evidence that IIT is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. IIT's Moffett Campus, where the NCFST is located, is a unique research facility which includes an industrial-size pilot plant and smaller pilot plants for food processing and packaging equipment, a pathogen containment pilot plant, a biotechnology laboratory, a packaging laboratory, analytical laboratories, offices, containment facilities, classrooms, and support facilities which permit research from benchtop to industrial-scale. The industrial-size pilot plant is built to accommodate routine food processing and packaging research in a commercial atmosphere. The physical layout of the facility provides maximum versatility in the use and arrangement of equipment of both commercial and pilot size, and in the capability to operate simultaneously several different pieces of equipment without interference with each other. In addition to facilities to conduct routine processing research, there are facilities suitable for more complex research, notably a pathogen containment pilot plant research facility, funded by the State of Illinois, which can also accommodate biotechnology scaleup and downstream processing and purification research. Other facilities include smaller containment facilities in which research involving use of components that may be potentially hazardous, such as pathogens in pasteurization or modified atmosphere packaging research, may be conducted.

Since 1988, IIT has provided an environment in which scientists from diverse backgrounds—academia, government, and industry—have brought their unique perspectives to focus on contemporary issues of food safety. The NCFST functions as a neutral ground where scientific exchange about generic food safety issues occurs freely and is channeled into the design of cooperative food safety programs. The NCFST recently convened a meeting of national experts in aseptic processing of foods containing small particles to identify research required to establish the safety of the process and gain its approval in the United States. This process is used in other countries and has the advantages of providing consumers with shelf-stable, fresher tasting products. As a result of the research conducted by industry in response to the plan developed at NCFST, an aseptic process was approved by FDA. The NCFST has become a center of cutting edge technologies, such as high pressure processing, pulsed electric field processing, electrical resistance processing, and ultra violet processing. Ongoing research on packaging materials is focused on providing more alternatives for use with irradiation. A workshop, with participation by representatives of government, academia, and industry, was held to discuss the use of irradiation as an intervention to prevent microbial contamination of foods and the need for alternative packaging materials for use with this technology. This led to the development of cooperative research on the safety of polymeric packaging materials for in-package irradiation. This type of research fills existing gaps in knowledge and expertise associated with improving the safety of foods at a time when concern about food contamination and resultant illnesses is high.

This cooperative research will provide fundamental food safety information, in the public domain, for use by all segments of the food science community in product and process development, regulatory activities, academic programs, and consumer programs. A particular use of this type of data by both industry and public health agencies is in Hazard Analysis Critical Control Point (HACCP) programs. Food manufacturers will use the information in the design of HACCP programs, for use in their plants, which prevent food safety hazards before they occur and enhance the safety of the final product. Public health agencies can design specific investigational techniques to be applied to the HACCP systems used in manufacturing plants.

An academic degree program (which is not part of the cooperative agreement) in food safety science has been underway for 8 years at IIT. The program will produce graduates with a foundation in food science and technology with specialization in food safety. Graduates from this program will manage quality control, safety assurance, and HACCP programs in industry. They will design equipment and processes for use in the production and packaging of safe food products. In the public sector, regulatory and other public health organizations, these graduates will evaluate the adequacy of processing and packaging parameters to produce safe endproducts, and they will manage regulatory and information programs enhancing the safety of the food supply and consumer knowledge about the food supply. Graduate students from IIT and University of Illinois are gaining hands-on experience in food safety by participating in the cooperative food safety research program. Several Masters of Science degrees, which included research conducted on cooperative projects, have been granted in disciplines such as engineering by IIT since the inception of the NCFST.

Collaboration between the public and the private sector is an efficient means for both to remain current with scientific and technical accomplishments from a food safety perspective. These collaborative programs will produce generic knowledge and expertise to be used by all segments of the food processing and packaging industry, as well as by public health organizations, regulatory agencies, and academic institutions in the performance of their roles in the food science community. The trend toward use of HACCP in both the domestic and international food industry as a means of assuring safety of products and as a basis for harmonizing regulatory activities is but one example of the need for and use of this food safety knowledge and expertise. Technology transfer mechanisms, which are developing out of the cooperative food safety programs, will facilitate the movement of advanced food processing and packaging technologies into the marketplace, while assuring the safety of those products.

IV. Reporting Requirements

Program progress reports and financial status reports will be required annually, based on date of award. These reports will be due within 30 days after the end of the budget period. A final program progress report and financial status report will be due 90 days after expiration of the project period of the cooperative agreement.

V. Delineation of Substantive Involvement

Substantive involvement by the awarding agency is inherent in the cooperative agreement award. Accordingly, FDA will have substantial involvement in the program activities of the project funded by the cooperative agreement. Substantive involvement includes, but is not limited to, the following:

1. FDA will appoint a project officer or co-project officers who will actively monitor the FDA-supported program under this award.

2. FDA shall have prior approval on the appointment of all key administrative and scientific personnel proposed by the grantee.

3. FDA will be directly involved in the guidance and development of the

program and of the personnel management structure for the program.

4. FDA scientists will participate, with the grantee, in determining and carrying out the methodological approaches to be used. Collaboration will also include data analysis, interpretation of findings, and, where appropriate, coauthorship of publications.

Dated: July 15, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–18689 Filed 7–21–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2145]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); VICH GL11 Draft Guidance on Impurities in New Veterinary Medicinal Products; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH GL11 draft guidance for industry entitled ''Impurities in New Veterinary Medicinal Products'' provides guidance recommendations for applications for marketing authorizations on the content and qualification of impurities in new veterinary medicinal products produced from chemically synthesized new active substances not previously registered in a member state.

DATES: Submit written comments by August 23, 1999; FDA must receive comments before the deadline in order to ensure their consideration at the next VICH committee meeting, but the agency will accept comments after the deadline.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

Copies of the draft guidance entitled ''Impurities in New Veterinary Medicinal Products'' may be obtained on the Internet from the CVM home page at ''http://www.fda.gov/cvm/fda/TOCs/guideline.html''. Persons without Internet access may submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT:

Regarding the VICH: Sharon R. Thompson, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, e-mail ''sthompso@cvm.fda.gov''.

Regarding the draft guidance: Kevin J. Greenlees, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6977, e-mail ''kgreenle@cvm.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities, industry associations, and individual sponsors to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seeking scientifically based harmonized technical requirements for the development of pharmaceutical products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) for several years to develop harmonized technical requirements for the registration of human pharmaceutical products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the registration of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH meetings are held under the auspices of the Office International des Épizooties. The VICH Steering Committee is composed of member representatives from the European Commission; the European Medicines Evaluation Agency; the European Federation of Animal Health; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/ New Zealand, one representative from the industry in Australia/ New Zealand, one representative from MERCOSUR (Argentina, Brazil, Uruguay, and Paraguay), and one representative from Federacion Latino-Americana de la Industria para la Salud Animal. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative participates in the VICH Steering Committee meetings.

At a meeting held on October 20 through 22, l998, the VICH Steering Committee agreed that the draft guidance entitled ''Impurities in New Veterinary Medicinal Products'' should be made available for public comment. Comments will be considered by FDA and the VICH Quality Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidance and publish it as a future guidance.

This draft guidance, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulations (62 FR 8961, February 27, l997) . For example, the document has been designated as a draft ''guidance'' rather than a draft ''guideline.'' Since guidance documents are not binding, mandatory words such as ''must,'' ''shall,'' and ''will'' in the original VICH document have been substituted with ''should,'' unless the reference is to a statutory or regulatory requirement. Additionally, the term(s) ''veterinary medicinal products'' and ''veterinary pharmaceutical products'' may require revision to be consistent with product terms used in other VICH guidance documents.

This draft guidance represents the agency's current thinking on impurities