Board of Governors of the Federal Reserve System, July 17, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement To Support the Waste-Management Education and Research Consortium, New Mexico State University; Notice of Intent to Accept and Consider a Single Source Application

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 to the Waste-Management Education and Research Consortium (WERC), New Mexico State University, to support the Annual International Environmental Design Contest. The estimated amount is $100,000 per annum. Competition is limited because the WERC International Environmental Design Contest is the only college level environmental design competition of its kind.

DATES: Submit applications by August 21, 2000.

ADDRESSES: An application is available from and should be submitted to: Maura Stephanos, Grants Management Specialist, Grants Management Office (HFA–520), Division of Contracts and Procurement Management, Office of the Director, Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7183. (Applications hand-carried or commercially delivered should be addressed to rm. 2129, 5630 Fishers Lane, Rockville, MD 20857; 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: Maura Stephanos (address above).

Regarding the programmatic aspects: Wendy Buckler, Office of Plant and Dairy Foods and Beverages (HFS–300), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–2923.

SUPPLEMENTAL INFORMATION: This project is authorized under section 301 of the Public Health Service Act (the PHS Act) (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance at 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).

The Public Health Service (PHS) strongly encourages all award recipients to provide a smoke-free work place and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

I. Background

While the American food supply is among the safest in the world, every year there are still millions of Americans stricken by illness caused by the food they consume, and the very young and elderly die as a result. In 1997, the President announced his Food Safety Initiative (FSI), the goal of which is to reduce the annual incidence of foodborne illnesses by enhancing the safety of the nation's food supply. As directed, agencies are exploring ways to strengthen systems of coordination, surveillance, inspections, research, risk assessment, and education. Through a collaborative effort between the FDA, the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA), a report titled ''Food Safety from Farm to Table: A National Food Safety Initiative'' was released in May 1997.

Over the last several years, the detection of outbreaks of foodborne illnesses associated with domestic and imported fresh fruits and vegetables has also increased. Imports have doubled over the past 7 years and they are expected to increase by 30 percent by 2002. Thus, FDA is directing surveillance, inspection, compliance, and education efforts to detect and prevent harmful pathogens from reaching the consumer in a food safety ''farm to table'' approach. These food safety efforts apply to both domestic and imported produce. To that end, FDA and USDA issued a guidance document that is intended to assist the U.S. and foreign produce industry in enhancing the safety of domestic and imported produce by addressing common areas of concern in the growing, harvesting, sorting, packing, and distribution of fresh produce.

WERC is a program of the College of Engineering at New Mexico State University established in 1990 under a cooperative agreement with the U.S. Department of Energy. Starting in 1991, WERC has conducted an Annual Environmental Design Contest (Contest), which is a unique educational experience for students from throughout the world. The Contest is open to any 2-year, 4-year, or graduate degree institution. Since 1998, there has been a separate concurrent competition for high school students. The Contest provides an opportunity for students to apply all the theories they have learned and to develop innovative solutions for real environmental issues. Most of the problems in the past dealt with waste disposal, ground water contamination, nuclear waste treatment, and similar subjects. The scope of problems has recently been broadened to include food safety and disciplines such as microbiology.

Major engineering and physical science departments at leading U.S. universities and some foreign countries regularly compete in the Contest. In the ninth annual Contest in 1998 to 1999, 56 universities and 8 high school teams presented and demonstrated technical solutions combined with economics, public policy, regulations and other considerations vital to the environment.

Government and industry sponsors provide tasks for the Contest. The tasks are technological problems for which known solutions are not readily available.

In 1999, FDA entered a task entitled ''Detection of Human Waste on Imported Fresh Fruits and Vegetables'' for the Contest. There are several areas in the production of fresh fruits and vegetables that can contribute to food safety concerns. One of the areas is the use of municipal biosolids or sewage sludge (the treated by-product of human waste treatment) as a soil amendment for the production of fresh fruits and vegetables. Improperly treated sewage sludge represents a significant source of human pathogens. Because the consumption of produce contaminated by human waste poses a potential health risk, FDA is seeking a mechanism by which it can: (1) Determine if sewage sludge has been adequately treated to eliminate pathogenic microorganisms and (2) determine if fresh fruits and vegetables are contaminated on the surface by improper sewage sludge. Three schools selected the FDA task.

II. Purpose

FDA will be one of the sponsors for the Contest administered by WERC and will submit task(s) to be considered by the schools. The school teams' imagination, fresh ideas, and innovative solutions can be of great importance to

improving the safety of the American food supply.

WERC reviews the tasks, adjusts them to stay within Contest parameters, and publicizes the Contest within the academic community. WERC will discuss and work with FDA on revising the agency's task. FDA will work closely with WERC throughout the Contest; the agency can also have a minimum of four judges participate in the competition.

WERC announces the Contest in the fall. The competitors are self-selected and, they may come from anywhere in the world. The student teams and their faculty advisors can accept the challenge of one or more of the tasks.

The teams conduct research for potential solutions, develop a concept for a process to complete the task, and present their findings (including a bench-scale demonstration of their solution) during the competition that is held in April. The goal of the competition is to design, develop, and test actual environmental processes for real-world problems.

The Contest is conducted in four parts: (1) A paper that presents a full-scale process analysis and design, (2) an oral presentation, (3) a bench-scale process demonstration (with samples taken of the product for analysis), and (4) a poster board presentation. All of the above Contest elements are part of a process used to communicate and to advance ideas and projects towards implementation in today's business environment.

The judges for the competition come from all walks of life and are respected as leaders within their professional communities. They are selected from industry, government, and academia.

The judges will critique each student team's performance, the performance of the contestants against the guidance provided, and the technical merits and applicability of the team's proposed solutions. A preliminary judges' meeting is held each February to review and revise the criteria for judging the different tasks and to finalize the judging process for the upcoming Contest. The recommendations resulting from the meeting are recorded for subsequent Contests. The broad base of judges have expertise in the physical and biological sciences, engineering, business, economics, health and safety regulations, environmental regulations, public policy, and communications.

To enhance the learning experience, WERC provides feedback on the teams' performance after each Contest. The faculty advisor for each task will be provided with the high score, the low score, the average score, and the score for the paper, oral, bench-scale process, and poster. Related comments from the judges may also be provided.

Each year, WERC tries to bring new sponsors to the program to maintain diversity and to address current environmental problems.

III. Delineation of Substantive Involvement

FDA will have substantial involvement in the activities of the Contest being funded by the cooperative agreement. Substantive involvement includes, but is not limited to, the following:

1. FDA will work closely with WERC throughout the annual Contest. This may include involvement in the selection of appropriate tasks for the next year's contests, in order to assure that selected tasks are diversified and address current environmental problems. Such involvement may include participation by FDA staff in conference calls and at meetings as well as through correspondence. FDA staff may also act as judges.

2. As one of several sponsors of the contest, FDA will submit task(s) for the Contest. The task must: (1) Represent an actual environmental, waste management decontamination, or microbiological problem for which there is no known solution, or for which existing solutions do not meet the desired performance criteria and (2) be adaptable to a bench-scale demonstration within the limitations of the Contest. All submitted tasks are reviewed by WERC staff and discussed with the tasks' sponsors before the final selection is made. Priorities of the FDA and possible current health issues/topics may impact on future task(s) that would be submitted to WERC.

3. As a sponsor of the contest, FDA will also provide qualified judges, one being the project officer for the submitted task(s), for the Contest. All judges are bound by the WERC contest ethic to make as objective a decision as possible on the awards. If a judge has a precontest bias for or against a particular university, he or she will excuse themselves from judgment of that university. Other judges will be selected from other sponsoring companies or agencies and from industry, government, and academia.

IV. Review Procedures

The application submitted by the WERC will undergo a noncompetitive, dual peer review. The application will be reviewed for scientific and technical merit by a panel of experts in the subject field of the specific application. If the application is recommended for approval it will then be presented to the National Advisory Environmental Health Sciences Council for concurrence with the recommendations made by the first level reviewers. The final funding decision will be made by the Commissioner of Food and Drugs or her designee.

V. Reporting Requirements

A Program Progress Report and a Financial Status Report (FSR) (SF–269) are required. An original FSR and two copies shall be submitted to FDA's Grants Management Officer within 90 days of the budget expiration date of the cooperative agreement. Failure to file the FSR (SF–269) on time may be grounds for suspension or termination of the agreement. Progress reports will be required quarterly within 30 days following each fiscal year quarter (January 31, April 30, July 30, October 31), except that the fourth report will serve as the annual report and will be due 90 days after the budget expiration date. CFSAN program staff will advise the recipient of the suggested format for the Program Progress Report at the appropriate time. A final FSR (SF–269), Program Progress Report and Invention Statement, must be submitted within 90 days after the expiration of the project period, as noted on the Notice of Grant Award.

Program monitoring of recipients will be conducted on an ongoing basis and written reports will be reviewed and evaluated at least quarterly by the Project Officer and the Project Advisory Group. Project monitoring may also be in the form of telephone conversations between the Project Officer/Grants Management Specialist and the Principal Investigator and/or a site visit with appropriate officials of the recipient organization. The results of these monitoring activities will be duly recorded in the official file and may be available to the recipient upon request.

VI. Mechanism of Support

A. Award Instrument

Support for this program will be in the form of a cooperative agreement. This agreement will be subject to all policies and requirements that govern the research grant program of the PHS, including provisions of 42 CFR part 52 and 45 CFR part 74.

B. Length of Support

The length of support will be for up to 5 years. Funding beyond the first year will be noncompetitive and will depend on: (1) Satisfactory performance during the preceding year, and/or (2) the availability of Federal fiscal year funds.

VII. Submission Requirements

The original and two copies of the completed Grant Application Form PHS 398 (Rev. 4/98) with copies of the appendices for each of the copies, should be submitted to Maura Stephanos (address above). Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by the PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

VIII. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application which have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information, shall not be used or disclosed except for evaluation purposes.

Dated: July 10, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94D–0325]

International Conference on Harmonisation; Draft Revised Guidance on Impurities in New Drug Substances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a draft revised guidance entitled ''Q3A(R) Impurities in New Drug Substances.'' The draft revised guidance, which updates a guidance on the same topic published in the **Federal Register** of January 4, 1996 (the 1996 guidance), was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft revised guidance clarifies the 1996 guidance, adds information, and provides consistency with more recently published ICH guidances. The draft revised guidance is intended to provide guidance to applicants for drug marketing registration on the content and qualification of impurities in new drug substances produced by chemical syntheses and not previously registered in a country, region, or member State.

DATES: Submit written comments by September 18, 2000.

ADDRESSES: Submit written comments on the draft revised guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the draft revised guidance are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573. Single copies of the guidance may be obtained by mail from the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852, or by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Copies may be obtained from CBER's FAX Information System at 1–888–CBER–FAX or 301–827–3844.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Charles P. Hoiberg, Center for Drug Evaluation and Research (HFD–800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5169.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: 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 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, the Canadian Health Protection Branch, and the European Free Trade Area.

In October 1999, the ICH Steering Committee agreed that a draft revised guidance entitled ''Q3A(R) Impurities in New Drug Substances'' should be made available for public comment. The draft revised guidance is a revision of a guidance on the same topic published in the **Federal Register** of January 4, 1996 (61 FR 372). The draft revised guidance is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

In accordance with FDA's good guidance practices (62 FR 8961, February 27, 1997), this document is now being called a guidance, rather than a guideline.

The draft revised guidance is intended to provide guidance to applicants for drug marketing registration on the content and qualification of impurities in new drug substances produced by chemical syntheses and not previously registered in a country, region, or member State. The draft revised guidance is not intended to apply to new drug substances used during the clinical research stage of development or clinical trials. The draft revised guidance also does not apply to biological/biotechnological substances, peptides, oligonucleotides,