DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0220]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Pharmacogenomic Data Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 28, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0557. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Pharmacogenomic Data Submissions—(OMB Control Number 0910–0557)—Extension

The guidance provides recommendations to sponsors submitting or holding investigational new drug applications (INDs), new drug applications (NDAs), or biologics license applications (BLAs) on what pharmacogenomic data should be submitted to the Agency during the drug development process. Sponsors holding, and applicants submitting, INDs, NDAs, or BLAs are subject to FDA requirements for submitting to the Agency data relevant to drug safety and efficacy (21 CFR 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12).

The guidance interprets FDA regulations for IND, NDA, or BLA submissions, clarifying when the regulations require pharmacogenomics data to be submitted and when the submission of such data is voluntary. The pharmacogenomic data submissions described in the guidance that are required to be submitted to an IND, NDA, BLA, or annual report are covered by the information collection requirements under parts 312, 314, and 601 (21 CFR parts 312, 314, and 601) and are approved by OMB under control numbers 0910–0014 (part 312, INDs); 0910–0001 (part 314, NDAs and annual reports); and 0910–0338 (part 601, BLAs).

The guidance distinguishes between pharmacogenomic tests that may be considered valid biomarkers appropriate for regulatory decisionmaking, and other, less well-developed exploratory tests. The submission of exploratory pharmacogenomic data is not required under the regulations, although the Agency encourages the voluntary submission of such data.

The guidance describes the voluntary genomic data submission (VGDS) that can be used for such a voluntary submission. The guidance does not recommend a specific format for the VGDS, except that such a voluntary submission be designated as a VGDS. The data submitted in a VGDS and the level of detail should be sufficient for FDA to be able to interpret the information and independently analyze the data, verify results, and explore possible genotype-phenotype correlations across studies. FDA does not want the VGDS to be overly burdensome and time-consuming for the sponsor.

FDA has estimated the burden of preparing a voluntary submission described in the guidance that should be designated as a VGDS. Based on FDA's experience with these submissions over the past few years, and on FDA's familiarity with sponsors' interest in submitting pharmacogenomic data during the drug development process, FDA estimates that approximately four sponsors will submit approximately one VGDS each, and that, on average, each VGDS will take approximately 50 hours to prepare and submit to FDA.

In the **Federal Register** of February 6, 2014 (79 FR 7198), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Voluntary Genomic Data Submissions	4	1	4	50	200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09470 Filed 4–25–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0411]

Cooperative Agreement To Support the Illinois Institute of Technology's National Center for Food Safety and Technology

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for a cooperative agreement in support of the Illinois Institute of Technology (IIT), which supports the National Center for Food Safety and Technology (NCFST). The estimated amount of support in Fiscal Year (FY) 14 will be for up to $5 million (direct plus indirect costs), with the possibility of 4 additional years of support for up to $20 million, subject to the availability of funds. This award will improve public health by continued support of an applied research, education, and outreach program related to the safety of food processing technologies and processed foods.

DATES: Important dates are as follows:

1. The application due date is June 3, 2014.
2. The anticipated start date is September 2014.
3. The opening date is May 3, 2014.
4. The expiration date is June 4, 2014.

ADDRESSES: Submit the original paper application to Gladys Melendez (Bohler) and a copy to Mickey Parish at the following addresses: Mickey Parish, Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN), 5100 Paint Branch Pkwy., HFS–300, Rm. 3A–0264, College Park, MD 20740, 240–402–1728, *Mickey.Parish@fda.hhs.gov;* and Gladys Melendez (Bohler), Division of State Acquisitions, Agreements and Grants, Food and Drug Administration, (HFA–500), 5630 Fishers Lane, Rm. 2032, Rockville, MD 20857, 240–731–3905, *gladys.bohler@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://www.fda.gov/food/newsevents/default.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Funding Opportunity Number: RFA–FD–1–005.

Catalog of Federal Domestic Assistance Number: 93.103

A. Background

FDA has supported the NCFST under six previously awarded cooperative agreements (53 FR 15736; 56 FR 46189; 59 FR 24703; 64 FR 39512; 69 FR 25405; and 74 FR 26408). NCFST was established by IIT to bring together the food safety and technology expertise of academia, industry, and FDA for the purpose of supporting research and outreach efforts related to the safety of foods based on a common goal of enhancing the safety of the food supply for U.S. consumers. NCFST has been successful in developing research programs, such as those related to low-moisture foods, and outreach programs, such as those related to sprout safety; these successes were achieved as a result of NCFST partnering with industry, academia, and FDA.

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, 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. This award will improve public health by continued support of an applied research, education, and outreach program related to the safety of food processing technologies and processed foods.

B. Research Objectives

FDA recognizes that food production and processing technology is rapidly changing, that globalization of the food supply is increasing, and that the number and nature of the hazards associated with foods is rapidly evolving. FDA intends to maintain and facilitate the further development of NCFST for the purpose of enhancing food safety to benefit the public. NCFST is uniquely positioned as a key component of FDA's food protection program. Specifically, through the Center's science platforms the research at NCFST focuses on the development and validation of food processing and packaging technologies for safety and quality; investigation and development of preventive technologies targeted to reduce or eliminate harmful chemical and microbial contamination of foods, and laboratory method performance (including method validation) to address issues associated with FDA-regulated products. Additionally the development of an integrated collaborative food protection research/education/outreach program 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.

C. Eligibility Information

Competition is limited to the Illinois Institute of Technology. FDA believes that continued support of NCFST at IIT is appropriate because IIT is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. IIT's Moffett Center, where NCFST is located, is a unique research facility that includes an industrial-size pilot plant and smaller pilot plants for food processing and packaging equipment, a pathogen containment pilot plant, a packaging laboratory, analytical laboratories, offices, containment facilities, classrooms, a distance learning center, and support facilities, which permit research from bench top 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 simultaneously operate several different pieces of equipment without interference with each other. Additionally, NCFST has a Biosafety Level 3 pilot plant and laboratory, as well as a select agent laboratory to conduct studies with *Clostridium botulinum* and other select agents.

Since 1988, IIT has provided an environment in which scientists from diverse backgrounds such as academia, government, and industry have brought their unique perspectives to focus on contemporary issues of food safety. 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. NCFST has become a center of cutting edge technologies, such as high pressure processing, cold plasma processing, pulsed electric field processing, pulsed light processing, high power ultrasound processing, microwave processing, and