(NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC is requesting OMB approval for the EHS–Net National Voluntary Environmental Assessment Information System (NVEAIS) to collect data from foodborne illness outbreak environmental assessments routinely conducted by local, state, territorial, or tribal food safety programs during outbreak investigations. Environmental assessment data are not currently collected at the national level. The data reported through this information system will provide timely data on the causes of outbreaks, including environmental factors associated with outbreaks, and are essential to environmental public health regulators' efforts to respond more effectively to outbreaks and prevent future, similar outbreaks. This information system is specifically designed to link to CDC's existing disease outbreak surveillance system (National Outbreak Reporting System).

The information system was developed by the Environmental Health Specialists Network (EHS–Net), a collaborative project of CDC, the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and nine states (California, Connecticut, Georgia, Iowa, New York, Minnesota, Oregon, Rhode Island, and Tennessee). The network consists of environmental health specialists (EHSs), epidemiologists, and laboratorians. The EHS–Net has developed a standardized protocol for identifying, reporting, and analyzing data relevant to foodborne illness outbreak environmental assessments.

While conducting environmental assessments during outbreak investigations is routine for food safety program officials, however, reporting information from the environmental assessments to CDC is not. State, Local, Tribal, and Territorial food safety program officials are the respondents for this data collection—one official from each participating program will report environmental assessment data on outbreaks. These programs are typically located in public health or agriculture agencies and there are approximately 3,000 such agencies in the United States. Thus, although it is not possible to determine how many programs will choose to participate, as NVEAIS is voluntary, the maximum potential number of program respondents is approximately 3,000.

These programs will be reporting data on outbreaks, not their programs or personnel. It is not possible to determine exactly how many outbreaks will occur in the future, nor where they will occur. However, we can estimate, based on existing data that a maximum of 1,400 foodborne illness outbreaks will occur annually. Only those programs in the jurisdictions in which these outbreaks occur would report to NVEAIS. Thus, not every program will respond every year. Consequently, the respondent burden estimate is based on the number of outbreaks likely to occur each year. Assuming each outbreak occurs in a different jurisdiction, there will be one respondent per outbreak.

There are two activities associated with NVEAIS that require a burden estimate. The first is entering all requested environmental assessment data into NVEAIS. This will be done once for each outbreak and will take approximately 2 hours per outbreak.

The second activity is the manager interview that will be conducted at each establishment associated with an outbreak. Most outbreaks are associated with only one establishment; however, some are associated with multiple establishments. We estimate that a maximum average of 4 manager interviews will be conducted per outbreak. Each interview will take about 20 minutes.

The total estimated annual burden is 4,667 hours. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Food safety program personnel	Reporting environmental assessment data into electronic system.	1,400	1	2	2,800
Food safety program personnel	Manager interview	1,400	4	20/60	1,867
Total					4,667

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–9670 Filed 4–20–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0231]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Experience Reporting for Licensed Biological Products; and General Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed extension of the collection of information concerning requirements relating to FDA's adverse experience reporting (AER) for licensed biological products, and general records associated with the manufacture and distribution of biological products.

DATES: Submit either written or electronic comments on the collection of information by June 20, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *Juanmanuel.vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Adverse Experience Reporting for Licensed Biological Products; and General Records—21 CFR Part 600 (OMB Control Number 0910–0308)—Extension

Under the Public Health Service Act (42 U.S.C. 262), FDA may only approve a biologics license application for a biological product that is safe, pure, and potent. When a biological product is approved and enters the market, the product is introduced to a larger patient population in settings different from clinical trials. New information generated during the postmarketing period offers further insight into the benefits and risks of the product, and evaluation of this information is important to insure its safe use. FDA issued the AER requirements in part 600 (21 CFR part 600) to enable FDA to take actions necessary for the protection of the public health in response to reports of adverse experiences related to licensed biological products. The primary purpose of FDA's AER system is to identify potentially serious safety problems with licensed biological products. Although premarket testing discloses a general safety profile of a biological product's comparatively common adverse effects, the larger and more diverse patient populations exposed to the licensed biological product provides the opportunity to collect information on rare, latent, and long-term effects. In addition, production and/or distribution problems have contaminated biological products in the past. AER reports are obtained from a variety of sources, including manufacturers, patients, physicians, foreign regulatory agencies, and clinical investigators. Identification of new and unexpected safety issues through the analysis of the data in the AERS system contributes directly to increased public health protection. For example, evaluation of these safety issues enables FDA to take focused regulatory action. Such action may include, but is not limited to, important changes to the product's labeling (such as adding a new warning), coordination with manufacturers to ensure adequate corrective action is taken, and removal of a biological product from the market when necessary.

Section 600.80(c)(1) requires licensed manufacturers or any person whose name appears on the label of a licensed biological product to report each adverse experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days of initial receipt of the information by the licensed manufacturer. These reports are known as postmarketing 15-day alert reports. This section also requires licensed manufacturers to submit any followup reports within 15 calendar days of receipt of new information or as requested by FDA, and if additional information is not obtainable to maintain records of the unsuccessful steps taken to seek additional information. In addition, this section requires a person who submits an adverse action report to the licensed manufacturer rather than FDA to maintain a record of this action. Section 600.80(e) requires licensed manufacturers to submit a 15-day alert report for an adverse experience obtained from a postmarketing clinical study only if the licensed manufacturer concludes that there is a reasonable possibility that the product caused the adverse experience. Section 600.80(c)(2) requires licensed manufacturers to report each adverse experience not reported in a postmarketing 15-day alert report at quarterly intervals, for 3 years from the date of issuance of the biologics license, and then at annual intervals. The majority of these periodic reports are submitted annually since a large percentage of currently licensed biological products have been licensed longer than 3 years. Section 600.80(i) requires licensed manufacturers to maintain for a period of 10 years records of all adverse experiences known to the licensed manufacturer, including raw data and any correspondence relating to the adverse experiences. Section 600.81 requires licensed manufacturers to submit, at an interval of every 6 months, information about the quantity of the product distributed under the biologics license, including the quantity distributed to distributors. These distribution reports provide FDA with important information about products distributed under biologics licenses, including the quantity, certain lot numbers, labeled date of expiration, the fill lot numbers for the total number of dosage units of each strength or potency distributed (*e.g.,* fifty thousand per 10-milliliter vials), and date of release. FDA may require the licensed manufacturer to submit distribution reports under this section at times other than every 6 months. Under § 600.90, a licensed manufacturer may submit a waiver request for any requirements that apply to the licensed manufacturer under §§ 600.80 and 600.81. A waiver request submitted under § 600.90 must include supporting documentation.

Manufacturers of biological products for human use must keep records of each step in the manufacture and distribution of a product including any

recalls. These recordkeeping requirements serve preventative and remedial purposes by establishing accountability and traceability in the manufacture and distribution of products. These requirements also enable FDA to perform meaningful inspections. Section 600.12 requires, among other things, that records must be made, concurrently with the performance of each step in the manufacture and distribution of products. These records must be retained for no less than 5 years after the records of manufacture have been completed or 6 months after the latest expiration date for the individual product, whichever represents a later date. In addition, under § 600.12, manufacturers must maintain records relating to the sterilization of equipment and supplies, animal necropsy records, and records in cases of divided manufacturing responsibility with respect to a product. Under § 600.12(b)(2), manufacturers are also required to maintain complete records pertaining to the recall from distribution of any product. Furthermore, § 610.18(b) requires, in part, that the results of all periodic tests for verification of cultures and determination of freedom from extraneous organisms be recorded and maintained.

Respondents to this collection of information include manufacturers of biological products and any person whose name appears on the label of a licensed biological product. Under table 1 of this document, the number of respondents is based on the estimated number of manufacturers that are subject to those regulations or that submitted the required information to the Center for Biologics Evaluation and Research and Center for Drugs Evaluation and Research, FDA, in fiscal year (FY) 2010. Based on information obtained from the FDA's database system, there were 108 licensed biologics manufacturers. This number excludes those manufacturers who produce Whole Blood or components of Whole Blood and in-vitro diagnostic licensed products, because of the exemption under § 600.80(k). The total annual responses are based on the number of submissions received by FDA in FY 2010. There were an estimated 86,583 15-day Alert reports, 57,300 periodic reports, and 349 lot distribution reports submitted to FDA. The number of 15-day alert reports for postmarketing studies under § 600.80(e) is included in the total number of 15-day alert reports. FDA received 21 requests for waivers under § 600.90, of which 19 were granted. The hours per response are based on FDA experience. The burden hours required to complete the MedWatch Form for § 600.80(c)(1), (e), and (f) are reported under OMB Control No. 0910–0291.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
600.80(c)(1) and 600.80(e)	108	801.69	86,583	1	86,583
600.80(c)(2)	108	530.55	57,300	28	1,604,400
600.81	108	3.23	349	1	349
600.90	21	1	21	1	21
Total					1,691,353

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

Under table 2 of this document, the number of respondents is based on the number of manufacturers subject to those regulations. Based on information obtained from FDA's database system, there were 304 licensed manufacturers of biological products in FY 2010. However, the number of recordkeepers listed for § 600.12(a) through (e) excluding (b)(2) is estimated to be 131. This number excludes manufacturers of blood and blood components because their burden hours for recordkeeping have been reported under § 606.160 in OMB Control No. 0910–0116. The total annual records is based on the annual average of lots released in FY 2010 (6,752), number of recalls made (1,881), and total number of adverse experience reports received (143,883) in FY 2010. The hours per record are based on FDA experience.

FDA estimates the burden of this recordkeeping as follows:

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
600.12 [2]	131	51.54	6,752	32	216,064
600.12 (b)(2)	304	6.19	1,881	24	45,144
600.80(c)(1) and 600.80(i)	108	1,332.25	143,883	1	143,883
Total					405,091

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

[2] The recordkeeping requirements in § 610.18(b) are included in the estimate for § 600.12.

Dated: April 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9651 Filed 4–20–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0012]

Analgesic Clinical Trials Innovation, Opportunities, and Networks (ACTION) Initiative

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Analgesic Clinical Trials Innovation, Opportunities, and Networks (ACTION) Initiative. The goal of the ACTION Initiative is to streamline the discovery and development process for new analgesic drug products for the benefit of public health. The ACTION Initiative is being developed, in large part, through the establishment of a cooperative agreement with one or more organizations. The ACTION Initiative will address major gaps in scientific information, which can slow down analgesic clinical trials and analgesic drug development. FDA will support the ACTION Initiative under the authority of the Federal Food, Drug, and Cosmetic Act.

DATES: Important dates are as follows:

1. The application due date is June 8, 2011.

2. The anticipated start date is July 14, 2011.

3. The opening date is April 22, 2011.

4. The expiration date is June 9, 2011.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT: Igor Cerny, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3124, Silver Spring, MD 20993–0002, 301–796–4273, e-mail: *Igor.Cerny@fda.hhs.gov;* Vieda Hubbard, Office of Acquisitions and Grant Services, Food and Drug Administration, 5630 Fishers Lane (HFA–500), Rockville, MD 20857, 301–827–7177, e-mail: *vieda.hubbard@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://grants.nih.gov/grants/guide/* (select the "Request for Applications" link), *http://www.grants.gov/* (see "For Applicants" section) and/or *http://www.fda.gov/AboutFDA/PartnershipsCollaborations/PublicPrivatePartnershipProgram/ucm231130.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–11–006

93.103

A. Background

Despite the enormous advances in drug development over the past 2 or 3 decades (*e.g.,* drugs that cure cancer and biologic drug products that halt the progression of rheumatoid arthritis), the development of novel analgesic drug products has lagged behind. Indeed, to this day, the only analgesic drug products that are used widely and successfully are opioids, acetaminophen, and nonsteroidal anti-inflammatory agents, all of which have serious, potentially life-threatening toxicities, even when used properly. While there has been exploration at the earliest stages of drug development, there has been widespread reluctance on the part of the pharmaceutical industry to take novel products further into development. This is in no small part due to the often daunting task of demonstrating the efficacy of analgesics in clinical trials. Many experts in analgesic drug development believe that it is the design of the clinical trials that is at fault in this situation and that better trial designs will yield more successful results. This hypothesis is certainly supported by the frequent failures of clinical efficacy trials of opioid drug products, considering the well established effectiveness of these products from literally thousands of years of clinical experience. For these reasons, additional studies are needed to assess the confounding nature of analgesic clinical trials and analgesic drug development.

B. Research Objectives

Based on collaboration with FDA, key stakeholder input, best Government, academic, and industry practices, and knowledge gained through workshops, the Grantee will be responsible for developing, defining, and recommending projects as described in this section. Applicants should, at a minimum, address the following three overarching research domains in this section. The overall study design processes within each of these domains should be aligned with established strategic goals and provide results and recommendations in alignment with the objectives of the ACTION Initiative.

1. Data analysis of primarily group analgesic clinical trials data (databases) for relationships between assay sensitivity and metrics including, but not limited to, specific research designs and methodological features so as to inform the future design of analgesic clinical trials.

2. Scientific assessment of FDA's clinical trial databases and development of novel and alternative means of analyzing various pain scores in a manner that effectively considers variables, such as bias and interindividual variance.

3. Development of methodologies for the execution and transformation of pooled trial data from multiple relevant analgesic trials.

C. Eligibility Information

The following organizations/institutions are eligible to apply:

- Higher education institutions as defined in section 101 of the Higher Education Act of 1965 (or a consortium of such institutions).

The following types of higher education institutions are always encouraged to apply for National Institutes of Health support as public or private institutions of higher education:

- Hispanic serving institutions.
- Historically Black colleges and universities.
- Tribally controlled colleges and universities.
- Alaska Native and Native Hawaiian serving institutions.

Nonprofits other than institutions of higher education.

- A nonprofit organization described in section 501(c)(3) of the Internal Revenue Code of 1986, which is exempt from tax under section 501(a) of that code.

An eligible organization that wishes to enter into a collaborative agreement must provide an assurance that the entity will not accept funding for a Critical Path Public-Private Partnership project from any organization that manufactures or distributes products regulated by FDA unless the entity provides assurances in its agreement with FDA that the results of the Critical Path Public-Private Partnership project will not be influenced by any source of funding.

II. Award Information/Funds Available

A. Award Amount

It is anticipated that no more than $1 million will be allocated to this cooperative agreement. It is anticipated that a single award will be made.