culture that impact patient safety, such as: organizational learning, overall perceptions of safety, compliance with procedures, attitudes and frequency of error reporting, nonpunitive response to error, reasons errors occur, and employee teamwork. Through the proposed project, a reliable hospital patient safety culture survey will be developed and then made available to the public, to reduce the burden of hospitals in developing their own instruments, to reduce the proliferation and use of untested instruments, and to foster benchmarking across hospitals.

Method of Collection

The purpose of this pilot data collection is to gather enough survey responses to evaluate the internal consistency, reliability, response variability, and other psychometric properties of a newly developed survey, not to produce national estimates. Therefore, a purposive sample (hand-chosen, non-statistical sample) of 12 hospitals will suffice to participate in the study. Hospitals will be selected based on two factors: bed size and teaching vs. non-teaching status (2 large/teaching, 2 medium/teaching, 2 small/teaching, 2 large/non-teaching, 2 medium/non-teaching, 2 small/non-teaching).

Surveys will be distributed to 100 employees at each of the 12 sites (a total of 1,200 employees). A contact person at each hospital will be asked to select 100 employees using a systematic random sample of employees. The contact person at each hospital will distribute the paper surveys to the 100 selected employees at each site. For purposes of individual confidentiality, no individual identifiers will be used, so it will not be possible to track individual responses. Respondents will be instructed to mail their completed surveys directly to the research organization conducting the study using a postage-paid return envelope that will be provided. The hospitals will at no time have access to individual responses.

The survey will be distributed to a total of 1,200 hospital employees (100 individuals at each of 12 hospitals), with a target response rate of 75%, or 900 returned surveys. Standard techniques like using a prenotification letter, a cover letter of support from the hospital, a follow-up postcard, and distribution of a second survey will be used to achieve the target response rate. Respondents should take approximately 20 minutes to complete the survey. Therefore, we estimate that the respondent burden for completing the survey will be 300 hours (900 completes multiplied by 20 minutes per completed survey).

Estimated Annual Respondent Burden:

Date collection effort	Number of respondents	Estimated time per respondent (minutes)	Estimated total burden hours
Safety Culture Survey Pilot	900	20	300

Respondents will not be asked to maintain any records. No additional equipment purchases will be made to support data collection processes or record keeping. Respondents will incur no monetary cost in completing the survey.

Estimated Annual Costs to the Federal Government

The total cost to the Government for conducting this survey development project is approximately $227,000 which includes the cost of survey development, pretesting, data collection, analysis, preparation of survey administration procedures, and preparation of a final report. The estimated cost of the data collection component is $50,000, which includes labor costs, fringe expenses, administrative expenses, and costs associated with copying, postage, and telephone expenses.

Request for Comments

In accordance with the Paperwork Reduction legislation cited in the summary section above, comments on the AHRQ information collection proposal are requested with regard to any of the following:

(a) Whether the proposed collection of information is necessary for the proper performance of functions of the Agency, including whether the information will have practical utility;

(b) The accuracy of the Agency's estimate of the burden (including hours and costs) of the proposed collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information on respondents, including the use of automated collection techniques or other forms of information technology.

(d) Ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: September 17, 2002.

Carolyn M. Clancy,

Acting Director.

[FR Doc. 02–24184 Filed 9–20–02; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 67 FR 42268–71, dated June 21, 2002) is amended to restructure the Epidemiology and Surveillance Division, National Immunization Program.

Section C–B, Organization and Functions, if hereby amended as follows:

Delete the functional statement for the *Epidemiology and Surveillance Division (CJ3),* and insert the following:

(1) Directs all Program activities regarding epidemiology, national surveillance, research and technical consultation for pertussis, diphtheria, tetanus, polio, measles, mumps, rubella, varicella, smallpox, and the vaccines, and toxoids to prevent these diseases, has the lead responsibility for immunization safety, and takes an

active role in the development of immunization policy and vaccine recommendations in the United States; (2) collaborates with other CDC CIOs in epidemiologic studies and surveillance activities for influenza and pneumococcal disease; (3) provides medical and epidemiologic expertise and collaborates with other NIP Divisions and CDC CIOs in developing strategies to enhance immunization coverage of adults; (4) directs national surveillance of diphtheria, pertussis, tetanus, polio, *Haemophilus influenzae* type b (in collaboration with other CDC CIOs), measles, mumps, rubella, congenital rubella, varicella, complications arising from these diseases, and adverse events following vaccination; (5) monitors vaccine safety, and conducts scientific research to evaluate the safety of all currently available and new vaccines; (6) develops strategies for designated national and international vaccine-preventable disease control programs and/or disease elimination activities; (7) provides epidemic aid in collaboration with other CDC CIOs, during outbreaks of vaccine-preventable diseases and consultation to State and local health departments and to foreign countries on these diseases and their prevention; (8) provides consultation and assistance to public health professionals on vaccine-preventable diseases, vaccines, and biological products; (9) directs epidemiologic research to evaluate the efficacy, safety, and cost effectiveness of vaccines, and to study aspects of vaccine-preventable diseases relevant to immunization practice; (10) provides scientific and administrative support for the Advisory Committee on Immunization Practices in the development of vaccine policies and recommendations.

Delete the titles and functional statements for the *Vaccine Safety and Development Activity (CJ3–2)*, *Adult Vaccine-Preventable Diseases Branch (CJ33)*, and *Child Vaccine-Preventable Diseases Branch (CJ34)*, and insert the following:

Bacterial Vaccine Preventable Disease Branch (CJ35). (1) Conducts epidemiologic research and provides medical expertise on bacterial vaccines and vaccine-preventable disease, including diphtheria, pertussis, *Haemophilus influenzae* type b, tetanus, anthrax, and pneumococcal disease; (2) provides consultation on the use of vaccines and toxoids recommended to prevent these diseases; (3) provides consultation and support to State and local health departments in the investigation of epidemics and other problems associated with bacterial vaccine-preventable diseases, and recommends appropriate control measures; (4) conducts national surveillance and prepares and distributes surveillance information for diphtheria, pertussis, and tetanus; (5) in collaboration with other CDC CIOs, conducts surveillance and investigates outbreaks of *Haemophilus influenzae* type b disease and pneumococcal disease; (6) analyzes and prepares information and statements for the Advisory Committee on Immunization Practices and other advisory committees on diphtheria, pertussis, and tetanus, and in collaboration with other CDC CIOs, *Haemophilus influenzae* type b, anthrax, and pneumococcal disease; (7) evaluates the effectiveness of activities to prevent bacterial vaccine-preventable diseases; (8) conducts epidemiologic studies to determine efficacy and safety of vaccines and toxoids recommended to prevent bacterial vaccine-preventable diseases; (9) prepares and reviews articles based on study findings for publication in professional journals, and makes presentations at professional conferences; (10) provides scientific support to other CDC CIOs in the development of effective communications and techniques to prevent bacterial vaccine-preventable diseases; (11) collaborates with the WHO, the Pan American Health Organization, as well as other national and international agencies on investigating bacterial vaccine-preventable disease outbreaks, conducting surveillance and epidemiologic research, and developing strategies for the prevention and elimination of bacterial vaccine-preventable diseases.

Viral Vaccine Preventable Diseases Branch (CJ36). (1) Conducts epidemiologic research and provides medical expertise on viral vaccine-preventable diseases, including measles, mumps, rubella, polio, varicella, influenza, and smallpox; (2) provides consultation on the use of vaccines recommended to prevent these diseases; (3) provides consultation and support to State and local health departments in the investigation of epidemics and other problems associated with viral vaccine-preventable diseases, and recommends appropriate control measures; (4) conducts national surveillance and prepares and distributes surveillance information for measles, mumps, rubella, polio, and varicella; (5) in collaboration with other NIP Divisions and CDC CIOs, performs surveillance and other emergency response activities for viral vaccine-preventable diseases (*e.g.,* surveillance for suspected smallpox cases); (6) analyzes and prepares information and statements for the Advisory Committee on Immunization Practices and other advisory committees on measles, mumps, rubella, polio, and varicella, and in collaboration with other CDC CIOs, influenza, rotavirus, and smallpox disease; (7) evaluates the effectiveness of activities to prevent viral vaccine-preventable diseases; (8) conducts epidemiologic studies to determine efficacy and safety of vaccines recommended to prevent viral vaccine-preventable diseases; (9) prepares and reviews articles based on study findings for publication in professional journals, and makes presentations at professional conferences; (10) provides scientific support to other CDC CIOs in the development of effective communications and techniques to prevent viral vaccine-preventable diseases; (11) collaborates with the WHO, the Pan American Health Organization, as well as other national and international agencies on investigating viral vaccine-preventable disease outbreaks, conducting surveillance and epidemiologic research, and developing strategies for the prevention and elimination of viral vaccine-preventable diseases.

Immunization Safety Branch (CJ37). (1) Coordinates a national surveillance program for monitoring vaccine safety, in collaboration with the Food and Drug Administration (FDA); (2) collects, analyzes, and evaluates data to determine the safety of designated vaccines; (3) prepares and distributes surveillance information pertaining to the monitoring of adverse events following immunization; (4) conduct ad-hoc studies and investigations pertaining to adverse events following immunization; (5) coordinates studies using large linked data bases to evaluate the potential causal relationship of vaccination with specific health outcomes; (6) collaborates with other CDC CIOs, the FDA, the National Institute of Allergy and Infectious Diseases, the Health Resources and Services Administration, the Department of Defense, and the National Vaccine Program Office in development and execution of a coordinated national plan to improve immunization safety; (7) assists the National Vaccine Injury Compensation Program in analyzing data from cases seeking compensation; (8) provides consultation to State and local health departments pertaining to monitoring and reporting of adverse events following immunization; (9) prepares articles based on findings of studies for publication in professional

journals and presentation at professional conferences; (10) collaborates with partners to develop new and combined vaccines that can be integrated into national and international immunization programs; (11) participates in trials of new and combined vaccines; (12) participates in international as well as domestic vaccine safety research activities; and (13) conducts research and evaluates alternative approaches for administering vaccines to enhance safety.

Dated: September 12, 2002.

Julie Louise Gerberding,

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

[FR Doc. 02–24034 Filed 9–20–02; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0388]

Guidance for Industry on Establishing Pregnancy Exposure Registries; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration is announcing the availability of a final guidance entitled ''Establishing Pregnancy Exposure Registries.'' The guidance is intended to provide sponsors with guidance on how to establish pregnancy exposure registries to monitor the outcomes of pregnancies exposed to specific medical products.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Dianne L. Kennedy, Center for Drug Evaluation and Research (HFD–970), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2364, kennedyd@cder.fda.gov; or Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190, stifano@cber.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Establishing Pregnancy Exposure Registries.'' Pregnancy exposure registries are recognized as one method of obtaining information on risks associated with exposure to medical products during pregnancy. The guidance is intended to provide sponsors with recommendations on how to establish pregnancy exposure registries, to help ensure the quality and integrity of registry data, and to help ensure the adequacy of document registry research methods.

In June 1999, FDA announced the availability of a draft guidance entitled ''Establishing Pregnancy Registries'' (64 FR 30041, June 4, 1999). Comments received on the draft guidance revealed that several general areas of the guidance needed revision and/or clarification.

Based on the comments received and on discussions with FDA's Pregnancy Labeling Subcommittee of the Advisory Committee for Reproductive Health Drugs on June 3, 1999 (64 FR 23340) and March 28 to 29, 2000 (65 FR 10811), the agency revised and/or clarified several sections of the guidance, including (1) When it is recommended that a registry be conducted, (2) use of comparison groups, (3) promotion of a registry and (4) regulatory reporting requirements. In addition, the name of the guidance was changed from ''Pregnancy Registries'' to ''Pregnancy Exposure Registries'' to more accurately reflect the nature of these types of studies and to differentiate them from more classic retrospective registries (e.g., cancer registries and birth defect registries).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on pregnancy exposure registries. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/cber/guidelines.htm*. To obtain the guidance document by fax call the FAX Information System at 1–888–CBER-FAX or 301–827–3844.

Dated: September 16, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–24037 Filed 9–20–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

National Park Service

Information Collection; Request for Extension

AGENCY: National Park Service, Interior

ACTION: Notice of request for extension of a currently approved information collection.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the National Park Service's intention to request an extension for a currently approved information collection in support of its Concession Management Program.

DATES: Comments in this notice must be received no later than November 22, 2002.

ADDITIONAL INFORMATION OR COMMENTS: Contact Cynthia Orlando, Concession Program Manager, National Park Service, 1849 C Street, NW., (2410), Washington, DC 20240 or 202/513–7144.