Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

As part of the national tuberculosis (TB) elimination strategy, the American Thoracic Society and CDC have published recommendations for targeted testing for TB and treatment for latent TB infection (LTBI)(Morbidity and Mortality Weekly Report 2000;49[RR06];1–54). However, between October 2000 and September 2004, the CDC received reports of 50 patients with severe adverse events (SAEs) associated with the use of the two or three-month regimen of rifampin and pyrazinamide (RZ) for the treatment of LTBI; 12 (24%) patients died (Morbidity and Mortality Weekly Report 2003;52[31]:735–9). In 2004, CDC began collecting reports of SAEs associated with any treatment regimen for LTBI. For surveillance purposes, an SAE was defined as any drug-associated reaction resulting in a patient's hospitalization or death after at least one treatment dose for LTBI. During 2004 − 2008, CDC received 17 reports of SAEs in 15 adults and two children; all patients had received isoniazid (INH) and had experienced severe liver injury (Morbidity and Mortality Weekly Report 2010; 59:224–9).

Reports of SAEs related to RZ and INH have prompted a need for this project—a national surveillance system of such events. The objective of the project is to determine the annual number and temporal trends of SAEs associated with any treatment for LTBI in the United States. Surveillance of such events will provide data to support periodic evaluation of guidelines for treatment of persons with LTBI and revision.

The Centers for Disease Control and Prevention request approval for a 3-year reinstatement with change of the previously approved National Surveillance for Severe Adverse Events Associated with Treatment of Latent Tuberculosis Infection—(OMB No. 0920–0773, expires April 31, 2011). The changes include a shortened data collection form and an increase in the number of respondents. This project will continue the passive reporting system for SAEs associated with therapy for LTBI. The system will rely on medical chart review and/or onsite investigations by TB control staff.

Potential respondents are any of the 60 reporting areas for the national TB surveillance system (the 50 states, the District of Columbia, New York City, Puerto Rico, and 7 jurisdictions in the Pacific and Caribbean). Data will be collected using the data collection form for SAEs associated with LTBI treatment. Based on previous reporting, CDC anticipates receiving an average of 10 responses per year from the 60 reporting areas. The data collection form is completed by healthcare providers and health departments for each reported hospitalization or death related to treatment of LTBI and contains demographic, clinical, and laboratory information. CDC will analyze and periodically publish reports summarizing national LTBI treatment adverse events statistics and also will conduct special analyses for publication in peer-reviewed scientific journals to further describe and interpret these data.

The Food and Drug Administration (FDA) collects data on adverse events related to drugs through the FDA MedWatch Program. CDC is collaborating with FDA in the reporting of SAEs. Reporting will be conducted through telephone, e-mail, or during CDC site visits. In this request, CDC is requesting approval for approximately 60 burden hours annually, an estimated increase of 36 hours. This is due to an estimated increase of reports of SAEs after the publication of the MMWR report on SAEs in 2010. There are no costs to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Physicians	10	1	1	10
Nurses	10	1	4	40
Medical Clerk	10	1	1	10
Total				60

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–9671 Filed 4–20–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day-11–0792]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Daniel Holcomb, CDC Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Environmental Health Specialists Network (EHS–Net) National Voluntary Environmental Assessment Information System (NVEAIS)—New—National Center for Environmental Health

(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.