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 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

National Health Interview Survey (NHIS), (OMB No. 0920–0214)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability of the population of the United States.

The annual National Health Interview Survey is a major source of general statistics on the health of the U.S. population and has been in the field continuously since 1957. Clearance is sought for three years, to collect data for 2010, 2011, and 2012. This voluntary household-based survey collects demographic and health-related information on a nationally representative sample of persons and households throughout the country. Information is collected using computer assisted personal interviews (CAPI). A core set of data is collected each year while sponsored supplements vary from year to year. For 2010, supplement information will be collected on cancer, occupational injury, epilepsy, and child mental health. The child mental health component includes a follow-up study to assess the validity of a short series of questions for measuring mental distress in children.

In accordance with the 1995 initiative to increase the integration of surveys within the Department of Health and Human Services, respondents to the NHIS serve as the sampling frame for the Medical Expenditure Panel Survey conducted by the Agency for Healthcare Research and Quality. The NHIS has long been used by government, university, and private researchers to evaluate both general health and specific issues, such as cancer, diabetes, and access to health care. It is a leading source of data for the Congressionally-mandated ''Health US'' and related publications, as well as the single most important source of statistics to track progress toward the National Health Promotion and Disease Prevention Objectives, ''Healthy People 2010.''

There is no cost to the respondents other than their time.

ANNUALIZED BURDEN TABLE

Questionnaire (respondent)	Number of respondents	Number of responses per respondent	Average burden per response in hours	Total burden in hours
Screener Questionnaire (adult family member)	10,000	1	5/60	833
Family Core (adult family member)	33,000	1	23/60	12,650
Adult Core (sample adult)	25,000	1	17/60	7,083
Child Core (adult family member)	10,000	1	9/60	1,500
Adult Cancer (sample adult)	25,000	1	19/60	7,917
Child Cancer (adult family member)	10,000	1	1/60	167
Adult Occupational Injury (sample adult)	25,000	1	2/60	833
Adult Epilepsy (sample adult)	25,000	1	1/60	417
Child Mental Health (adult family member)	10,000	1	2/60	333
Child Mental Health Follow-Up (parent)	430	1	40/60	287
Child Mental Health Follow-Up (child)	319	1	28/60	149
Re-interview Survey)	.....	1	5/60	250
Total Burden Hours	.....	.....	.....	32,419

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–12393 Filed 5–27–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0050]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Importer's Entry Notice

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 June 29, 2009.

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: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0046. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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.

Importer's Entry Notice (OMB Control Number 0910–0046)—Extension

In order to make an admissibility decision for each entry, FDA needs four additional pieces of information that are not available in the U.S. Customs and Border Protection's (CBP's) dataset. These data elements are the FDA Product Code, FDA country of production, FDA manufacturer/shipper, and ultimate consignee. It is the ''automated'' collection of these four data elements for which OMB approval is requested. FDA construes this request as an extension of the prior approval of collection of this data via a different media, i.e., paper. There are additional data elements which filers can provide to FDA along with other entry-related information which, by doing so, may result in their receiving an FDA admissibility decision more expeditiously, e.g., the quantity, value, and Affirmation(s) of Compliance with Qualifier(s).

At each U.S. port of entry (seaport, landport, and airport) where foreign-origin FDA-regulated products are offered for import, FDA is notified, through CBP's Automated Commercial System (ACS) by the importer (or his agent) of the arrival of each entry. Following such notification, FDA reviews relevant data to ensure the imported product meets the standards as are required for domestic products, makes an admissibility decision, and informs the importer and CBP of its decision. A single entry frequently contains multiple lines of different products. FDA may authorize specific lines to enter the United States unimpeded, while others in the same entry are to be held pending further FDA review/action.

An important feature developed and programmed into FDA's automated system is that all entry data passes through a screening criteria program. FDA's electronic screening criteria module makes the initial screening decision on every entry of foreign-origin FDA-regulated product. Virtually instantaneously after the entry is filed, the filer receives FDA's admissibility decision covering each entry, i.e., ''MAY PROCEED'' or ''FDA REVIEW.''

Examples of FDA's need to further review an entry include: Products originating from a specific country or manufacturer known to have a history of problems, FDA has no previous knowledge of the foreign manufacturer and/or product, or an import alert covering the product has been issued, etc. The system assists FDA entry reviewers by notifying them of information, such as the issuance of import alerts, thus averting the chance that such information will be missed.

With the inception of the interface with CBP's ACS, FDA's electronic screening criteria program is applied nationwide. This virtually eliminates problems such as ''port shopping,'' e.g., attempts to intentionally slip products through one FDA port when refused by another, or to file entries at a port known to receive a high volume of entries. Every electronically submitted entry line of foreign-origin FDA-regulated product undergoes automated screening described previously. The screening criteria can be set to be as specific or as broad as applicable; changes are virtually immediately effective. This capability is of tremendous value in protecting the public in the event there is a need to immediately halt a specific product from entering the United States.

In the **Federal Register** of February 25, 2009 (74 FR 8549), FDA published a 60-day notice requesting comments on the information collection requirements for FDA regulated products. Two comments were received.

One comment was submitted by the American Association of Exporters and Importers. General comments expressed support for the automation of the data elements sought by FDA. A second comment encouraged FDA to pursue risk management methodologies which will reduce FDA's dependence on transaction data for admissibility decisions. The comments encouraged FDA to develop risk management methodologies using account management techniques assessing the internal controls of foreign manufacturers and U.S. importers will provide FDA with better insight into admissibility decisions before entry of the merchandise.

FDA agrees that risk management methodologies are key to effective and efficient oversight of FDA regulated commodities. However, different commodities may have different risk factors and being able to identify the commodity, where it was manufactured, and who shipped the commodity are essential for FDA to determine the risk factors that should be applied when the product is offered for entry. These data elements are key for FDA in order to apply the appropriate risk strategy.

A second comment was submitted by Organon Schering-Plough. No specific comments were provided about the collection of the additional FDA data elements. The submission suggested that FDA develop a process similar to the ''binding ruling'' process that is maintained by CBP because of the impact on the filers compliance-score rating. However, the development of a ''binding ruling'' process is outside the scope of this announcement.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3,727	1,070	3,988,371	.263	1,048,447

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

Dated: May 20, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–09–08AW]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Quarantine Station Illness Response Forms: Airline, Maritime, and Land/Border Crossing—Existing Collection in Use without an OMB Number—National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC proposes to collect patient-level clinical, epidemiologic, and demographic data from ill travelers and their possible contacts in order to fulfill its regulatory responsibility to prevent the importation of communicable diseases from foreign countries (42 CFR Part 71) and interstate control of communicable diseases in humans (42 CFR Part 70).

Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States. The regulations that implement this law, 42 CFR Parts 70 and 71, authorize quarantine officers and other personnel to inspect and undertake necessary control measures with respect to conveyances (*e.g.*, airplanes, cruise ships, trucks, etc.), persons, and shipments of animals and etiologic agents in order to protect the public health. The regulations also require conveyances to immediately report an ''ill person'' or any death on board to the Quarantine Station prior to arrival in the United States. An ''ill person'' is defined in statute by:

— Fever (≥100° F or 38° C) persisting ≥48 hours.

— Fever (≥100° F or 38° C) and rash, glandular swelling, or jaundice.

— Diarrhea (≥3 stools in 24 hours or greater than normal amount).

The Severe Acute Respiratory Syndrome (SARS) situation and concern about pandemic influenza and other communicable diseases have prompted CDC Quarantine Stations to recommend that *all* illnesses be reported prior to arrival.

CDC Quarantine Stations are currently located at 20 international U.S. Ports of Entry. When a suspected illness is reported to the Quarantine Station, officers promptly respond to this report by meeting the incoming conveyance (when possible), collecting information and evaluating the patient(s), and determining whether an ill person can safely be admitted into the U.S. If Quarantine Station staff is unable to meet the conveyance, the crew or medical staff of the conveyance is trained to complete the required documentation and forward it (using a secure system) to the Quarantine Station for review and follow-up.

To perform these tasks in a streamlined manner and ensure that all relevant information is collected in the most efficient and timely manner possible, Quarantine Stations use a number of forms—the Airline Screening and Illness Response Form, the Ship Illness/Death Reporting Form, and the Land/Border Crossing Form—to collect data on passengers with suspected illness and other travelers/crew who may have been exposed to an illness. These forms are also used to respond to a report of a death aboard a conveyance.

The purpose of all of the forms is the same: to collect information that helps quarantine officials detect and respond to potential public health communicable disease threats. All forms collect the following categories of information: demographics and mode of transportation, clinical and medical history, and any other relevant facts (*e.g.*, travel history, traveling companions, etc.). As part of this documentation, quarantine public health officers look for specific signs and symptoms common to the nine quarantinable diseases (Pandemic influenza; SARS; Cholera; Plague; Diphtheria; Infectious Tuberculosis; Smallpox; Yellow fever; and Viral Hemorrhagic Fevers), as well as most communicable diseases in general. These signs and symptoms include fever, difficulty breathing, shortness of breath, cough, diarrhea, jaundice, or signs of a neurological infection. The forms also collect data specific to the traveler's conveyance.

These data are used by Quarantine Stations to make decisions about a passenger's suspected illness as well as its communicability. This in turn enables Quarantine Station staff to assist conveyances in the public health management of passengers and crew.

The estimated total burden on the public, included in the chart below, can vary a great deal depending on the severity of the illness being reported, the number of contacts, the number of follow-up inquiries required, and who is recording the information (*e.g.*, Quarantine Station staff versus the conveyance medical authority). In all cases, Quarantine Stations have implemented practices and procedures that balance the health and safety of the American public against the public's desire for minimal interference with their travel and trade. Whenever possible, Quarantine Station staff obtain information from other documentation (*e.g.*, manifest order, other airline documents) to reduce the amount of the public burden.

There is no cost to respondents other than their time to complete the survey. The estimated annual burden for this data collection is 172 hours.

ESTIMATE OF ANNUALIZED BURDEN

Respondents	Form	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Quarantine Staff / Crew or Medical Staff	Airline Illness or Death Investigation Form	1320	1	6/60