(0920–0821, expires 9/30/2012), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting a revision to an existing data collection of 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 2003 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 in person (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 are unable to meet the conveyance, the crew or medical staff of the conveyance are 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 Air Travel Illness or Death Investigation Form, Maritime Conveyance Illness or Death Investigation Form, and the Land Travel Illness or Death Investigation 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 three forms is the same: To collect information that helps quarantine officials detect and respond to potential public health communicable disease threats. All three 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. The total estimated burden requested for this data collection is 377 hours.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–12–0556]

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) 639–7570 or send an email to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Assisted Reproductive Technology (ART) Program Reporting System (0920–0559, exp. 9/30/2012)—Revision—National Center for Chronic Disease and Public Health Promotion (NCDDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The ART program reporting system is used to comply with Section 2(a) of Pub. L. 102–493 (known as the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA)), 42 U.S.C. 263a–1(a)). FCSRCA requires each ART program to annually report to the Secretary through the CDC pregnancy success rates achieved by each ART program, the identity of each embryo laboratory used by such ART program, and whether the laboratory is certified or has applied for certification under the Act. The reporting system allows CDC to publish an annual success rate report to Congress as specified by the FCSRCA.

CDC requests OMB approval to continue information collection for three years. This Revision request includes an increase in the total estimated burden hours due to an increase in the estimated number of

responding clinics and an increase in the estimated number of responses per respondent. In addition, this Revision request describes implementation of a brief, one-time optional feedback survey at the end of the data submission for each reporting year. The feedback survey will elicit information about ART reporting system usability as well as respondents' perspectives on the usefulness of the information collection.

Information is collected electronically through the National ART Surveillance System (NASS), a web-based interface, or by electronic submission of NASS-compatible files. The NASS includes information about all ART cycles initiated by any of the ART programs practicing in the United States and its territories. The system also collects information about the pregnancy outcome of each cycle as well as a number of data items deemed important to explain variability in success rates across ART programs and individuals.

Respondents are the 484 ART programs in the United States. Approximately 440 ART programs are expected to report an average of 339 ART cycles each. The burden estimate includes the time for collecting, validating, and reporting the requested information. Information is collected on an annual schedule.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 96,960.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
ART Programs	NASS	440	339	39/60
	Feedback Survey	176	1	2/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-12–0338]

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) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S. (OMB No. 0920–0338, exp. 9/30/2012)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), Office on Smoking and Health (OSH) has the primary responsibility for the Department of Health and Human Services (HHS) smoking and health program. HHS's overall goal is to reduce death and disability resulting from the use of smokeless tobacco products and other forms of tobacco use through programs of information, education and research.

Since 1994, as required by the Comprehensive Smokeless Tobacco Education Act of 1986 (CSTHEA, 15 U.S.C. 4401 et seq., Pub. L. 99–252), CDC has collected information about the ingredients used in smokeless tobacco products and their nicotine content. Respondents are commercial smokeless tobacco product manufacturers, packagers, or importers (or their designated representatives), who are required by the CSTHEA to submit ingredient reports to HHS on an annual basis. The legislation also authorizes HHS to undertake research, and to report to Congress, as deemed appropriate, about the health effects of these ingredients.

Respondents are not required to submit specific forms; however, they are required to meet reporting guidelines and to submit the ingredient report by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting practices for other companies currently required to report ingredients added to other consumer products. Typically, respondents submit a summary report to CDC with the ingredient information for multiple products, or a statement that there are no changes to their previously submitted ingredient report.

Ingredient reports for new products are due at the time of first importation. Thereafter, ingredient reports are due annually on March 31. Information is submitted to OSH by mailing a written report on the respondent's letterhead, by CD, three-inch floppy disk, or thumb drive. The information collection is subject to strict confidentiality provisions and electronic mail submissions are not accepted. Upon receipt and verification of the annual nicotine and ingredient report, OSH issues a Certificate of Compliance to the respondent.

OMB approval is requested for three years. There are no changes to information collection procedures or the estimated burden per response. Due to an increase in the estimated number of respondents (from 11 to 13), there is an increase in the total estimated annualized burden hours (from 18,843 to 22,269). There are no costs to respondents other than their time.