**Proposed Project**

**National Disease Surveillance Program–I—Case Reports—Revision—National Center for Emerging and Zoonotic Infectious Disease (NCEZID), Centers for Disease Control and Prevention (CDC)**

*Background and Brief Description*

Surveillance of the incidence and distribution of disease has been an important function of the US Public Health Service (PHS) since an 1878 Act of Congress, which authorized the PHS to collect morbidity reports. After the Malaria Control in War Areas Program had fulfilled its original 1942 objective of reducing malaria transmission, its basic tenets were carried forward and broadened by the formation of the Communicable Disease Center (CDC) in 1946. CDC was conceived of as a well-equipped, broadly staffed agency used to translate facts about analysis of morbidity and mortality statistics on communicable diseases and through field investigations.

The surveillance emphasis has shifted as certain diseases have declined in incidence, national emergencies have prompted involvement in new areas, and other diseases have taken on new aspects. Surveillance for the following diseases was approved three years ago: Creutzfeldt-Jakob Disease (CJD), Cyclosporiasis cayetanensis, Q Fever, Dengue, Reye Syndrome, Hantavirus pulmonary syndrome (HPS), Tick-borne Rickettsial Disease, Kawasaki syndrome, Trichinosis, Legionellosis, Tularemia, Lyme Disease (LD), Typhoid Fever, Malaria, Viral Hepatitis, and Plague. Due to change requests and surveillance systems moving to and receiving information collection approval under OMB Control number 0920–0728 (National Notifiable Diseases Surveillance System (NNDSS)) during the last three years, the following diseases/conditions are now included in this program: Creutzfeldt-Jakob Disease (CJD), Reye Syndrome, Kawasaki syndrome, and Acute Flaccid Myelitis. CDC needs to continue this surveillance package for another three years to maintain continuity in these surveillance systems. The data throughout the years are used to monitor the occurrence of non-notifiable conditions and to plan and conduct prevention and control programs at the state, territorial, local and national levels.

CDC currently collects data for certain diseases in summary form under OMB Control number 0920–0004, (National Disease Surveillance Program II—Disease Summaries). These disease summaries are for important, yet different types of infections from those covered in this disease case reports request. Maintaining separate OMB Control number approvals for these two types of data collections assists CDC in managing the two surveillance activities.

CDC works with state health departments to propose, coordinate, and evaluate nationwide surveillance systems. State epidemiologists are responsible for the collection, interpretation, and transmission of medical and epidemiological information to CDC.

The original purpose for reporting communicable diseases was to determine the prevalence of diseases dangerous to public health. However, collecting data also provided the basis for planning and evaluating effective programs for prevention and control of infectious diseases. Current information on disease incidence is needed to study present and emerging disease problems. CDC coordination of nationwide reporting maintains uniformity so that comparisons can be made from state to state and year to year.

In addition to development of prevention and control programs, surveillance data serves as statistical material for those engaged in research or medical practice, aid to health education officials and students, and data for manufacturers of pharmaceutical products. Annual surveillance data are published in the MMWR Surveillance Summary. The total burden requested is 190 hours, a decrease in 11,257 hours since the last submission. This is due to the other diseases reporting moving to the Notifiable Diseases Surveillance System (0920–0728). There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hrs.) |
|---|---|---|---|---|
| Epidemiologist | CJD | 20 | 2 | 20/60 |
| Epidemiologist | Kawasaki Syndrome | 55 | 8 | 15/60 |
| Epidemiologist | Reye Syndrome | 50 | 1 | 20/60 |
| Epidemiologist | Acute Flaccid Myelitis | 100 | 1 | 30/60 |
| Total | | | | |

**Leroy Richardson,**

*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2015–31706 Filed 12–16–15; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[60Day–16–0821; Docket No. CDC–2015–0114]**

### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed revision of an information collection request entitled

''Quarantine Station Illness Response Forms: Airline, Maritime, and Land/Border Crossing'' which will enable CDC to collect information concerning cases of illness or death that occur during or after travel to the United States in order to determine if further public health follow-up is required.

**DATES:** Written comments must be received on or before February 16, 2016.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC–2015–0114 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

**Please note:** All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below. 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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

**Proposed Project**

Quarantine Station Illness Response Forms: Airline, Maritime, and Land/Border Crossing (0920–0821, expires 04/30/2016). Revision. Division of Global Migration and Quarantine, National Center for Emerging Zoonotic and Infectious Diseases, Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

CDC is requesting approval for a revision to this existing information collection with the intent of ensuring that CDC can continue and improve the collection of pertinent information related to communicable disease or deaths that occur aboard conveyances during travel within the United States and into the United States from a foreign country, as authorized under 42 Code of Federal Regulations part 70 and 71, respectively.

Concerning routine operations, CDC is adjusting its estimates of respondents and burden associated with the use of the Air Travel, Maritime Conveyance, and Land Travel Illness or Death Investigation forms.

- CDC is requesting an increase in the number of respondents to the Air Travel Illness or Death Investigation form, from 1626 respondents to 1800. This results in an additional 15 hours of burden per year.
- CDC is requesting fewer respondents to the Maritime Conveyance Illness or Death Investigation Form, from 1873 to 750 reports. This results in a decrease of 94 hours.
- CDC is requesting a decrease in the number of respondents to the Land Travel Illness or Death Investigation form, from 259 respondents to 100. This results in a decrease of 13 hours.

Also included are adjustments to the number of respondents and estimated burden to the public for the use of the United States Traveler Health Declaration and Ebola Risk Assessment forms at U.S. ports of entry. These forms are currently used to collect contact information and assess travelers' risk for Ebola if they are coming to the United States from Sierra Leone and Guinea. The adjustments are as follows:

- CDC is requesting 40,238 fewer respondents to the United States Traveler Health Declaration (English: Hard Copy, fillable PDF, electronic portal), resulting in a decrease of 10,060 burden hours.
- CDC is requesting an additional 6,814 respondents to the United States Traveler Health Declaration (French translation guide), with an increase of 1,703 burden hours.
- CDC is requesting 76 fewer respondents for the United States Traveler Health Declaration (Arabic translation guide), with a decrease of 19 burden hours.
- CDC is requesting 2,637 fewer respondents to the Ebola Risk Assessment Form (English hard copy), and an associated decrease of 659 burden hours.
- CDC is requesting an increase of 141 respondents to the Ebola Risk Assessment (French translation guide) and an increase of 35 burden hours.
- CDC is requesting eight fewer respondents to the Ebola Risk Assessment (Arabic translation guide) and two fewer burden hours.

CDC is also requesting an adjustment to the number of respondents and burden hours for the use of the Interactive Voice Response (IVR) system surveys.

- CDC is requesting 40,238 fewer respondents to the IVR Active Monitoring Survey (English: Recorded), with 56,333 fewer burden hours.
- CDC is requesting an increase of 6,814 respondents to the IVR Active Monitoring Survey (French: Recorded) and an additional 9,540 burden hours.
- CDC is requesting 76 fewer respondents to the IVR Active Monitoring: Arabic translation

assistance (no script), with a decrease of 106 burden hours.

These adjustments result in a decrease of 55,994 burden hours.

CDC requested a total of 38,817 respondents and 29,388 burden hours annually. The respondents to these information collections are travelers and ship medical personnel. There is no cost to respondents other than the time required to provide the information requested.

ESTIMATED ANNUALIZED BURDEN HOURS

| Respondent | Form | Number of respondents | Number of responses per respondent | Average burden per response (in minutes) | Total burden hours |
|---|---|---|---|---|---|
| Traveler | Airline Travel Illness or Death Investigation Form. | 1,800 | 1 | 5/60 | 150 |
| Ship Medical Personnel | Maritime Conveyance Illness or Death Investigation Form. | 750 | 1 | 5/60 | 63 |
| Traveler | Land Travel Illness or Death Investigation Form. | 100 | 1 | 5/60 | 8 |
| Traveler | Ebola Risk Assessment Form (Ill traveler interview: English, French, Arabic, or other as needed). | 100 | 1 | 15/60 | 25 |
| Traveler | United States Traveler Health Declaration (English: Hard Copy, fillable PDF, electronic portal). | 9,000 | 1 | 15/60 | 2250 |
| Traveler | United States Traveler Health Declaration (French translation guide). | 8,400 | 1 | 15/60 | 2100 |
| Traveler | United States Traveler Health Declaration (Arabic translation guide). | 100 | 1 | 15/60 | 25 |
| Traveler | Ebola Risk Assessment Form (English hard copy). | 810 | 1 | 15/60 | 203 |
| Traveler | Ebola Risk Assessment French translation guide. | 252 | 1 | 15/60 | 63 |
| Traveler | Ebola Risk Assessment Arabic translation guide. | 5 | 1 | 15/60 | 1 |
| Traveler | IVR Active Monitoring Survey (English: Recorded). | 9,000 | 21 | 4/60 | 12,600 |
| Traveler | IVR Active Monitoring Survey (French: Recorded). | 8,400 | 21 | 4/60 | 11,760 |
| Traveler | IVR Active Monitoring: Arabic translation assistance (no script). | 100 | 21 | 4/60 | 140 |
| Total | | 38,817 | | | 29,388 |

**Leroy A. Richardson,**

*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–D–0164]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act

**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 January 19, 2016.

**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: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0734. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

**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.

### Guidance for Industry on Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act, OMB Control Number 0910–0734—Extension

Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(o)(4)) authorizes FDA to require, and if necessary, order labeling changes if FDA becomes aware of new safety information that FDA believes should be included in the labeling of certain prescription drug and biological products approved under section 505 of the FD&C Act or section 351 of the PHS Act (42 U.S.C. 262). Section 505(o)(4) of the FD&C Act applies to prescription