DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–08–07BN]

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

Study to Assess Hepatitis Risk (STAHR)—New—National Center for AIDS Viral Hepatitis and TB Prevention, (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Hepatitis C is the most prevalent bloodborne infection in the United States. Approximately 3.2 million persons are chronically infected with hepatitis C virus (HCV).

Identifying and reaching persons at risk for HCV infection is critical to prevent infection. Currently the Centers for Disease Control and Prevention (CDC) monitor the national incidence of acute hepatitis C through passive surveillance of acute, symptomatic cases of laboratory confirmed hepatitis C cases. However, only a small group of people with acute infection exhibit symptoms (<25%). Passive surveillance only captures a small fraction of acutely infected people. Injection drug users (IDUs) are the primary risk group for acute hepatitis C. Thus, it is necessary to consider strategies other than passive surveillance for incidence monitoring. One such strategy is to conduct serial cross-sectional seroprevalence surveys among populations at increased risk of infection. Better methods of identification of persons at risk will enhance current surveillance efforts.

The purpose of the proposed study is to develop and test different methods to recruit a sample of young IDUs at risk for HCV infection. These recruitment methods will be compared and contrasted to identify a methodology to be used in ongoing serial cross-sectional seroprevalence surveys. CDC is requesting approval for two years.

Working with the University of California, San Diego (UCSD), the project will recruit a total of 1000 young IDUs during the 2 years using several methods. These methods are street outreach, respondent driven sampling and venue based. They are to be conducted in a sexually transmitted disease clinic and syringe exchange program. Young IDUs who consent to participate will be administered an eligibility interview questionnaire by a trained field staff member. If found eligible, the participant will take an audio-computer assisted self interview that includes questions on drug use and sexual behavior, HCV and Human Immunodeficiency Virus (HIV) status, knowledge of HCV, and missed opportunities for hepatitis prevention. The project will also collect blood samples from each consenting participant to test for HCV infection and hepatitis A and B vaccination without cost. Participants needing medical and/or drug treatment services will be referred to the appropriate services.

Participation in the data collection is voluntary and there is no cost to respondents other than their time. The total estimated annual burden hours are 816.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Young IDUs	Screener	1000	1	5/60
Eligible young IDUs	Survey	800	1	55/60

Dated: July 1, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–15630 Filed 7–9–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–08–0576]

Agency Forms Undergoing Paperwork Reduction Act Review

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Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920–0576)—Revision—Division of Select Agents and Toxins (DSAT), Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER), Centers for Disease Control and Prevention (CDC). The revisions to the data collection are primarily changes to the guidance documents and forms to clarify instructions, correct editorial errors from previous submission, and reformat the structure of the forms based on the day-to-day processing of these forms. This request is for approval for three years.

Background and Brief Description

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A of Public Law 107–188 (42 U.S.C. 262a), requires the United States Department of Health and Human Services (HHS) to regulate the possession, use, and transfer of biological agents or toxins (i.e., select agents and toxins) that could pose a severe threat to public health and safety. The Agricultural Bioterrorism Protection Act of 2002, Subtitle B of Public Law 107–188 (7 U.S.C. 8401),

requires the United States Department of Agriculture (USDA) to regulate the possession, use, and transfer of biological agents or toxins (i.e., select agents and toxins) that could pose a severe threat to animal or plant health, or animal or plant products. In accordance with these Acts, HHS and USDA promulgated regulations requiring entities to register with the CDC or the Animal and Plant Health Inspection Service (APHIS) if they possess, use, or transfer a select agent or toxin (42 CFR part 73, 7 CFR part 331, and 9 CFR part 121). CDC and APHIS coordinate regulatory activities for those agents that would be regulated by both agencies (''overlap'' select agents). CDC and APHIS adopted an identical system to collect information for the possession, use, and transfer of select agents and toxins.

CDC is requesting continued OMB approval to collect this information through the use of five forms. The forms are: (1) Application for Registration, (2) Request to Transfer Select Agent or Toxin, (3) Report of Theft, Loss, or Release of Select Agent and Toxin, (4) Report of Identification of Select Agent or Toxin, and (5) Request for Exemption. The Application for Registration (42 CFR, 73.7(d)) will be used by entities to register with CDC. Entities may amend their registration (42 CFR, 73.7(h)1)) if any changes occur.

The Request to Transfer Select Agent or Toxin form (42 CFR 73.16) will be used to request transfer of a select agent or toxin to their facility. CDC, with APHIS, has revised the form by requiring the recipient to submit the initial request, be notified by the sender of the expected shipment date, and verify if the shipment did not occur.

The Report of Theft, Loss, or Release of Select Agent and Toxin form (42 CFR 73.19(a)(b)) must be completed by entities if there is theft, loss, or release of a select agent or toxin. The Report of Identification of Select Agent or Toxin form 42 CFR 73.5(a)(b) and 73.6(a)(b)) will be used by clinical and diagnostic laboratories to notify CDC that select agents or toxins identified as the result of diagnostic or proficiency testing have been disposed of in a proper manner. The form will be used by Federal law enforcement agencies to report the seizure and final disposition of select agents and toxins. CDC has revised the Report of Identification of Select Agent or Toxin form to ensure duplicate reports are not submitted by requesting the entity that makes the final identification report the select agents or toxins identified as the result of diagnostic or verification testing.

The Request for Exemption form (42 CFR 73.5(d)(e) and 73.6(d)(e)) will be used by entities that use an investigational product that are, bear, or contain select agents or toxins or in cases of public health emergency. An entity may apply to HHS for an exclusion of an attenuated strain of a select agent or toxin that does not pose a severe threat to public health and safety (42 CFR 73.3(e)(1) and 73.4(e)(1)).

This regulation outlines situations in which an entity must notify or may make a request of HHS in writing. An entity may apply to the HHS Secretary for an expedited review of an individual by the Attorney General (42 CFR 73.10(e)). CDC has not developed standardized forms for these situations. The entity should provide the information in the appropriate section of the regulation.

As part of the requirements of the Responsible Official, the Responsible Official is required to conduct regular inspections (at least annually) of the laboratory where select agents or toxins are stored. Results of these self-inspections must be documented (42 CFR 73.9(a)(5)).

As part of the training requirements of this regulation, the entity is required to record the identity of the individual trained, the date of training, and the means used to verify that the employee understood the training (42 CFR 73.15(c)).

An individual or entity may request administrative review of a decision denying or revoking certification of registration or an individual may appeal a denial of access approval (42 CFR 73.20). An entity must implement a system to ensure certain records and databases are accurate and that the authenticity of records may be verified (42 CFR 73.17(b).

Prior to issuance of a certificate of registration, CDC inspects entities to ensure compliance with this regulation (42 CFR 73.18).

The estimated annual burden is 9,657 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

CFR reference	Data collection	Number of respondents	Responses per respondent	Average burden per response (in hours)
73.7(d)	Registration Application	5	1	4.5
73.7(h)(1)	Amendment to Registration Application	264	5	1
73.19(a)(b)	Notification of Theft, Loss, or Release form	60	1	1
73.5 & 73.6(d–e)/73.3 & 73.4(e)(1)	Request for Exemption/Exclusion	5	1	1
73.16	Request to Transfer Select Agent or Toxin	264	4	1.5
73.5 & 73.6(a)(b)	Report of Identification of Select Agent or Toxin form.	264	10	1
73.10(e)	Request expedited review	10	1	30/60
73.9(a)(5)	Documentation of self-inspection	264	1	1
73.15(c)	Documentation of training	264	1	2
73.20	Administrative Review	15	1	4
73.17	Ensure secure recordkeeping system	264	1	4
73.18	Inspections	264	1	8

Dated: July 2, 2008.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–15749 Filed 7–9–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Refugee Resettlement

AGENCY: Office of Refugee Resettlement, Administration for Children and Families.

ACTION: Single-Source Program Expansion Supplement.

CFDA#: 93.583.

Legislative Authority: The Refugee Act of 1980 as amended, Wilson-Fish Amendment, 8 U.S.C. 1522(e)(7); section 412(e)(7)(A) of the Immigration and Nationality Act.

Amount of Award: $1,312,414 supplement for current year.

Project Period: 09/30/2005–09/29/2010.

Justification for the Exception to Competition: The Wilson-Fish program is an alternative to the traditional State-administered welfare system for providing integrated assistance and services to refugees, asylees, Amerasian Immigrants, Cuban and Haitian Entrants, and Trafficking Victims. San Diego County is one of 12 sites that has chosen this alternative approach.

The supplemental funds will allow the grantee, Catholic Charities Diocese of San Diego, to provide refugee cash assistance through the end of this fiscal year to eligible refugees (and others eligible for refugee benefits) under the San Diego Wilson-Fish Program.

The primary reason for the grantee's supplemental request is a higher number of arrivals than anticipated when the grantee's budget was submitted and approved last year. The Refugee Act of 1980 mandates that the Office of Refugee Resettlement (ORR) reimburse States and Wilson-Fish projects for the costs of cash and medical assistance for newly arriving refugees. Since 1991, ORR has reimbursed States and Wilson-Fish agencies for providing cash and medical assistance to eligible individuals during their first eight months in the United States.

Hence, the supplement is consistent with the purposes of the Wilson-Fish Program, the Refugee Act of 1980, and ORR policy.

FOR FURTHER INFORMATION CONTACT: Carl Rubenstein, Wilson-Fish Program Manager, Office of Refugee Resettlement, Aerospace Building, 8th Floor West, 901 D Street, SW., Washington, DC 20447. Telephone: 202–205–5933.

Dated: July 1, 2008.

David H. Siegel,

Acting Director, Office of Refugee Resettlement.

[FR Doc. E8–15633 Filed 7–9–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0381]

Draft Guidance for Industry on Voluntary Third-Party Certification Programs for Foods and Feeds; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Voluntary Third-Party Certification Programs for Foods and Feeds.'' This draft guidance describes the general attributes FDA believes a voluntary third-party certification program should have in order to help ensure its certification is a reliable reflection that the foods and feeds from certified establishments are safe and meet applicable FDA requirements.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by September 8, 2008.

ADDRESSES: Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sharon Lindan Mayl, Food and Drug Administration, 5600 Fishers Lane (HF–11), Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Voluntary Third-Party Certification Programs for Foods and Feeds.'' This draft guidance is issued in response to the recommendations contained in the Action Plan for Import Safety: A Roadmap for Continual Improvement (Action Plan) issued on November 6, 2007, by the Interagency Working Group on Import Safety (Working Group) established by Executive Order 13439, as well as FDA's Food Protection Plan released on the same date. Both those plans emphasize certification as a way to help verify the safety of products from a growing food establishment inventory, both domestic and foreign.

In the **Federal Register** of April 2, 2008 (73 FR 17989), FDA issued a notice requesting comments on the use of third-party certification programs for foods and animal feeds. FDA received approximately 70 comments in response to that notice. The comments were generally supportive of the use of third-party certification programs. Many encouraged FDA to recognize such programs as a way to increase participation and improve the safety and security of foods.

This draft guidance, when finalized, will represent FDA's current thinking on the certification process and will describe the general attributes FDA believes a voluntary third-party certification program should have in order to provide FDA with confidence in that program. If FDA has such confidence, we may choose to recognize the program and provide incentives for establishments to obtain certification by recognized certification programs. Recognition in this context means that FDA has determined that certification may be a reliable reflection that the foods from the certified establishment are safe and meet applicable FDA requirements. Such recognition would be tailored to particular categories of products and would occur in a separate document that builds upon the general attributes set forth in this document. Therefore, this draft guidance is intended as one of the steps in FDA's future recognition of one or more voluntary third-party certification programs for particular product types.

To further that process, FDA is also announcing, in a separate notice issued in this **Federal Register**, a voluntary pilot program for third-party certification bodies that certify foreign processors of aquacultured shrimp. This pilot is intended to gather technical and operational information that will assist