

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30 Day–15–15AIS]

**Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management

and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

CDC Burden of Canine Brucellosis Information Collection—New—National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Canine brucellosis is a bacterial infection caused by the organism *Brucella canis*. Few seroprevalence studies have been done to estimate the prevalence of canine brucellosis, most of which were conducted over 25 years ago. Two recent reports from Oklahoma and Wisconsin describe increasing prevalence in dogs; however, the national burden is not known. *B. canis* is also pathogenic to humans, although human infections are thought to be rare in the United States.

Unlike *Brucella abortus*, *B. melitensis*, and *B. suis*, *B. canis* is not classified as a select agent. As a result, laboratory identification of the organism in humans does not require reporting to the Laboratory Response Network.

*Brucella* species-specific data are not collected in the Nationally Notifiable Disease Surveillance System at CDC, and there are no validated *Brucella canis* serological tests to diagnose disease in humans. For these reasons, there are no national estimates of *B. canis* prevalence in humans or canines.

Additionally, canine infections with other *Brucella* species have been reported in the literature. Zoonotic transmission is a concern with all *Brucella* species pathogenic to humans, and at least one human infection with *B. suis* related to canine contact has been reported. Neither the prevalence of canine brucellosis nor the potential risk of zoonotic spread to humans is known.

There has been interest in human brucellosis caused by *B. canis* among the public health community. However, the degree of public health importance of human *B. canis* infections has not yet been ascertained. The Council of State

and Territorial Epidemiologists approved a position statement in 2012 that recommends increased focus on *B. canis*, and urges CDC to support the development of a human diagnostic assay.

The purpose of this information collection request is to estimate the burden of canine brucellosis in the United States, which will aid in the determination of the level of public health importance of human *B. canis* infections, and the potential for transmission of brucellosis from dogs. An estimate of disease burden in dogs will provide an idea of potential transmission between dogs and humans, and determine the need for future human public health studies, which is critical during this time of scarce resources.

Veterinary diagnostic laboratories throughout the United States will be solicited to provide information on the quantity of test requests and positive results for *Brucella spp.* in canines, outsourcing of clinical testing, state-wide policies for reporting of positive results, and policies for human exposure to clinical specimens or isolates.

The laboratories were identified through multiple sources: A review of the Animal and Plant Health Inspection Service-approved *Brucella* diagnostic laboratories, the National Animal Health Laboratory Network laboratories, the American Association of Veterinary Laboratory Diagnosticians (AAVLD), and an internet search.

The outcomes of this information collection are to assess the burden of disease in the animal host (dogs, in this case), as well as evaluate the knowledge and practices of occupational exposures to the organism. The information collected will be used to guide a longer term strategy for identification of human cases, understanding risk factors and activities associated with zoonotic transmission, and eventually validation of a human diagnostic assay. These strategies will be implemented using other mechanisms.

The total annual burden is 139 hours.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Veterinary diagnostic laboratory staff .....	Burden of Canine Brucellosis Information Collection.	119	1	1
Non-responders (over estimation) .....	Telephone script .....	119	1	5/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Other laboratories .....	Burden of Canine Brucellosis Information Collection.	10	1	1
Total				

**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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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Tribal TANF Data Report, TANF Annual Report, and Reasonable Cause/

Corrective Action Documentation Process.  
*OMB No.:* 0970-0215.  
*Description:* 42 U.S.C. 612 (Section 412 of the Social Security Act as amended by Public Law 104-193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA)), mandates that federally recognized Indian Tribes with an approved Tribal TANF program collect and submit to the Secretary of the Department of Health and Human Services data on the recipients served by the Tribes' programs. This information includes both aggregated and disaggregated data on case characteristics and individual characteristics. In addition, Tribes that

are subject to a penalty are allowed to provide reasonable cause justifications as to why a penalty should not be imposed or may develop and implement corrective compliance procedures to eliminate the source of the penalty. Finally, there is an annual report, which requires the Tribes to describe program characteristics. All of the above requirements are currently approved by OMB and the Administration for Children and Families is simply proposing to extend them without any changes.

*Respondents:* Indian Tribes.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Final Tribal TANF Data Report .....	70	4	451	126,280
Tribal TANF Annual Report .....	70	1	40	2,800
Tribal TANF Reasonable Cause/Corrective .....	70	1	60	4,200

*Estimated Total Annual Burden Hours:* 133,280.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-7285, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**  
*Reports Clearance Officer.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-N-2102]

**Syed Huda: Debarment Order**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debaring Syed Huda from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Huda was convicted of two felonies under Federal law for conduct relating to the regulation of a drug product. Mr. Huda was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Huda failed to respond. Mr. Huda's failure to respond constitutes a waiver of his right to a hearing concerning this action.

**DATES:** This order is effective September 16, 2015.

**ADDRESSES:** Submit applications for special termination of debarment to the Division of Dockets Management (HFA-