

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.*
 [FR Doc. 2015-23226 Filed 9-15-15; 8:45 am]
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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.

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, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.
 [FR Doc. 2015-23179 Filed 9-15-15; 8:45 am]
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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 debarment 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-

305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Kenny Shade (ELEM-4144) Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act.

On May 16, 2014, the U.S. District Court for the Eastern District of Virginia entered judgment against Mr. Huda for one count of importation contrary to law, in violation of 18 U.S.C. 545 and 2, one count of introducing misbranded drugs into interstate commerce, in violation of 21 U.S.C. 331(a), 333(a)(2), and 18 U.S.C. 2, one count of unlicensed wholesale distribution of prescription drugs, in violation of 21 U.S.C. 331(t), 333(b)(1)(D), 353(e)(2)(A), and 18 U.S.C. 2, and one count of wire fraud, in violation of 18 U.S.C. 1343.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for this conviction is as follows: Mr. Huda was a cofounder and co-owner of Gallant Pharma International Inc. (Gallant Pharma), between August 2009 and August 2013. Gallant was a company dedicated to the illegal importation and sale of misbranded and non-FDA approved chemotherapy drugs and injectable cosmetic drugs and devices in the United States.

As cofounder and co-owner of Gallant Pharma, Mr. Huda was primarily responsible for the United States based portion of the conspiracy, including: (1) Identifying a drop shipper willing to accept illegal importations of behalf of Gallant Pharma, (2) locating space for Gallant Pharma to store misbranded and non-FDA approved drugs and devices, (3) establishing relationships with customers in the Washington, DC metropolitan area, (4) interviewing and hiring sales representatives in other parts of the United States, and (5) establishing merchant accounts with credit card processors, for receipt of illegal proceeds via wire transfer into Canadian bank accounts. Gallant Pharma was not licensed as a prescription drug wholesaler by the

Commonwealth of Virginia. Some of the drugs and devices that Mr. Huda acquired were not approved by the FDA for use on patients in the United States. Mr. Huda admitted that the drugs sold by Gallant Pharma were prescription only; and were misbranded in that, among other things, they did not bear adequate directions for use and were not subject to an exemption from that requirement; and they were accompanied by non-FDA approved packaging and inserts. The drugs Gallant Pharma sold also lacked the FDA-required pedigree, which protects patient health by tracking each sale, purchase, or trade of a drug from the time of manufacturing to delivery to the patient.

Immediately after establishing Gallant Pharma's presence in the Eastern District of Virginia, on or about September 25, 2009, Mr. Huda received a cease and desist letter from a law firm on behalf of Medicis, the exclusive authorized marketer of RESTYLANE and PERLANE in the United States and Canada. The letter informed Gallant Pharma that its marketing of these drugs violated the FD&C Act and could subject Gallant Pharma to substantial criminal and civil penalties. The letter included Gallant Pharma's marketing materials, which falsely claimed that Gallant Pharma had been "strictly working with the current FDA rules and regulations for almost 10 years."

Mr. Huda personally solicited orders on behalf of Gallant Pharma, and on or about October 19, 2010, he sold 10 vials of misbranded TAXOTERE to a physician in Oceanside, CA, in exchange for \$2450, thereby causing misbranded drugs to travel in interstate commerce from the Eastern District of Virginia. Mr. Huda was aware of several occasions in which physicians complained after receiving drugs with packaging and inserts written in language other than English, and he authorized a price reduction upon receiving such complaints.

Between August 2009 and August 2013, Gallant Pharma received illegal proceeds of at least \$12,400,000 from the sale of misbranded and non-FDA approved drugs and devices in the United States. Mr. Huda admitted that he was an organizer or leader of this criminal activity and that his actions were in all respects knowing, voluntary, and intentional, and did not occur by accident, mistake, or for another innocent reason.

As a result of his conviction, on May 20, 2015, FDA sent Mr. Huda a notice by certified mail proposing to permanently debar him from providing services in any capacity to a person that

has an approved or pending drug product application. The proposal was based on the finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Huda was convicted of felonies under Federal law for conduct related to the regulation of a drug product. The proposal also offered Mr. Huda an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal was received on May 26, 2015. Mr. Huda failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and has waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Syed Huda has been convicted of felonies under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Syed Huda is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see DATES)(see section 201(dd), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act (21 U.S.C. 321(dd), 335a(c)(1)(B), and 335a(c)(2)(A)(ii)). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Syed Huda, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Huda provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act. In addition, FDA will not accept or review any abbreviated new drug applications from Syed Huda during his period of debarment (section 306(c)(1)(B) of the FD&C Act.

Any application by Mr. Huda for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No.

FDA–2014–N–2102 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–23204 Filed 9–15–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Synaptic Plasticity in Alzheimer's Disease.

Date: November 6, 2015.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Maurizio Grimaldi, MD, Ph.D., Scientific Review Officer, National Institute On Aging, National Institutes Of Health, 7201 Wisconsin Avenue, Room 2c218, Bethesda, MD 20892, 301–496–9374, grimaldim2@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: September 10, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–23229 Filed 9–15–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Hazardous Waste Worker Training

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the (NIEHS), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

ADDRESSES: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Joseph T. Hughes, Jr., Director, Worker Training Program, Division of Extramural Research and Training, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number (919) 541–0217 or Email your request, including your address to: hughes3@niehs.nih.gov. Formal requests for additional plans and instruments must be requested in writing. Proposed Collection: Hazardous Waste Worker Training—42 CFR part 65, 0925–0348, Expiration Date 12/31/2015 –EXTENSION, National Institute

of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

SUPPLEMENTARY INFORMATION: This request for OMB review and approval of the information collection is required by regulation 42 CFR part 65(a)(6). The National Institute of Environmental Health Sciences (NIEHS) was given major responsibility for initiating a worker safety and health training program under Section 126 of the Superfund Amendments and Reauthorization Act of 1986 (SARA) for hazardous waste workers and emergency responders. A network of non-profit organizations that are committed to protecting workers and their communities by delivering high-quality, peer-reviewed safety and health curricula to target populations of hazardous waste workers and emergency responders has been developed. In twenty-eight years (FY 1987–2015), the NIEHS Worker Training program has successfully supported 20 primary grantees that have trained more than 3.3 million workers across the country and presented over 194,000 classroom and hands-on training courses, which have accounted for nearly 39 million contact hours of actual training. Generally, the grant will initially be for one year, and subsequent continuation awards are also for one year at a time. Grantees must submit a separate application to have the support continued for each subsequent year. Grantees are to provide information in accordance with S65.4 (a), (b), (c) and 65.6(a) on the nature, duration, and purpose of the training, selection criteria for trainees' qualifications and competency of the project director and staff, cooperative agreements in the case of joint applications, the adequacy of training plans and resources, including budget and curriculum, and response to meeting training criteria in OSHA's Hazardous Waste Operations and Emergency Response Regulations (29 CFR 1910.120). As a cooperative agreement, there are additional requirements for the progress report section of the application. Grantees are to provide their information in hard copy as well as enter information into the WTP Grantee Data Management System. The information collected is used by the Director through officers, employees, experts, and consultants to evaluate applications based on technical merit to determine whether to make awards. *Frequency of Response:* Biannual. *Affected Public:* Non-profit organizations. *Type of Respondents:* Grantees. The annual reporting burden is as follows: *Estimated Number of*