

Proposed Project: Sickle Cell Disease and Other Hemoglobinopathies Program Evaluation—[NEW]

Background: In response to the growing need for resources devoted to sickle cell disease and other hemoglobinopathies, Congress, under Section 501(a)2 of the Social Security Act (2000), authorized the appropriation of funds for enabling the Secretary to provide for special projects of regional and national significance, research and training with respect to maternal and child health and children with special health care needs the following: Genetic disease testing, counseling and information development and dissemination programs, for grants relating to hemophilia without regard to age, and for the screening of newborns for sickle cell anemia and other genetic disorders, and follow-up services. As stated in House Report No. 107–229 regarding the Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Bill 2002, the purpose of the Sickle Cell Disease and Newborn Screening Program (SCDNBSP) is “to enhance the sickle cell disease newborn screening program and its locally based outreach and counseling efforts.” In addition, the American Jobs Creation Act of 2004, Public Law 108–357, states that “* * * the Bureau of Primary Health Care and the Maternal and Child Health Bureau, shall conduct a demonstration program by making grants for up to 40 eligible entities, for each fiscal year in which the program is conducted under this section, for the purpose of developing and establishing systemic mechanisms to improve the

prevention and treatment of Sickle Cell Disease.” (See 42 U.S.C. 300b–1).

Purpose: HRSA’s activities under the legislative authorities relative to the Sickle Cell Disease and Newborn Screening Program (SCDNBSP) have been delegated to the Maternal and Child Health Bureau (MCHB), Genetic Services Branch (GSB). The MCHB’s GSB supports seventeen community based organizations and the National Coordinating and Evaluation Center for the Sickle Cell Disease and Newborn Screening Program (SCDNBS) in addition to nine cooperative agreements and a National Coordinating Center for the Sickle Cell Disease Treatment Demonstration Program (SCDTDP). An evaluation will be conducted to assess the service delivery processes and quality of the system of care delivered by grantees under the Newborn Screening Program to individuals affected by Sickle Cell disease who present at their sites for care. The Centers for Disease Control and Prevention defines Hemoglobinopathies as “a group of disorders affecting red blood cells. SCD and Thalassemia are included in this group.” (See http://www.cdc.gov/ncbddd/sicklecell/RuSH_FAQs.html). The information from the evaluation will be used to evaluate the grantees’ performance in achieving the objectives of the hemoglobinopathies program during the grant period, assess the breadth of grantees’ outreach to emerging populations affected by hemoglobinopathies and the needs of those populations attempting to access services. Data collection tools for which OMB approval is being requested are as

follows: (1) The Minimum Database Project Sickle Cell Disease (MDP SCD) Questionnaire, (2) the Minimum Database Project Sickle Cell Trait/Carrier (MDP SCT) Questionnaire, and (3) the MDP Hemoglobinopathies Emerging Populations Questionnaire.

Respondents: The MDP SCD and the MDP SCT Questionnaires will be administered by grantees to clients or caregivers when they present for services. At the time of enrollment, SCDNBSP participants will be informed about the data collection and clients will be asked to participate in either the SCD questionnaire or the SCT questionnaire depending on their disease or carrier status. The program will enroll participants on a rolling basis such that new patients will be added to the program as they present for services and provide consent. Data will be collected at two points annually for the SCD Questionnaire, the first, when clients and caregivers are enrolled into the SCDNBS Program and the second, at follow-up after enrollment. Data will be collected once annually for the SCT Questionnaire. The Hemoglobinopathies Emerging Populations Form serves as a stand alone form for the other HRSA hemoglobinopathies programs, with its content. These questions are also embedded in the MDT SCD and MDP SCT questionnaires. The HRSA hemoglobinopathies programs also plan to use this questionnaire in developing educational materials, prioritizing outreach activities and informing decisions for future funding requests.

The annual estimate of burden is as follows:

Questionnaires	Number of respondents	Responses per respondent	Total responses	Average hours per response	Total hour burden	Wage rate	Total hour cost
MDP SCD Questionnaire	140	2	280	.45	126	\$20.90	\$2,633.40
MDP SCT Questionnaire	1,400	1	1,400	.30	420	20.90	8,778.00
Hemoglobinopathies Emerging Populations Form	*1,125	2	*2,250	.20	450	20.90	9,405.00
Total	2,665	3,930	996	20,816.40

E-mail comments to paperwork@hrsa.gov or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: August 19, 2010.
Sahira Rafiullah,
Director, Division of Policy and Information Coordination.
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BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0213]

Su Van Ho: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) debaring Su Van Ho for a period of 15 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Ho was convicted of three felonies under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Ho was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of July 15, 2010, Mr. Ho failed to respond. Mr. Ho's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective August 26, 2010.

ADDRESSES: Submit applications for 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, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-632-6844.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the act (21 U.S.C. 335a(b)(3)(A)), that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On August 4, 2009, the United States District Court for the Central District of California accepted Mr. Ho's guilty plea and entered judgment against him for the offenses of: Smuggling, Causing an Act to be Done in violation of 18 U.S.C. 545, Concealing a Material Fact by Trick or Device in violation of 18 U.S.C. 1001(a)(1) and Receipt of an Adulterated Food and Delivery Thereof for Pay in violation of 21 U.S.C. 331(c), 333(a)(1), and 342(a)(3).

FDA's finding that debarment is appropriate is based on the three felony convictions referenced herein for conduct relating to the importation into the United States of any food. The factual basis for those convictions is as follows: Between at least January 1,

2003, through September 16, 2004, Mr. Ho owned and operated Vincent Seafood and Trading, a frozen seafood import and distribution business. On or about August 20, 2004, in violation of 18 U.S.C. 545 and 2(b), Mr. Ho knowingly and willfully, with the intent to defraud the United States, did pass and cause to be passed through the customhouse a fraudulent commercial invoice that falsely described 610 cartons of Frozen Silk Worm as "Frozen Dade" fish and 461 cartons of Pineapple Brand Betel Nut as "Frozen Palmnut."

On or about September 16, 2004, in violation of 18 U.S.C. 1001(a)(1), Mr. Ho knowingly and willfully concealed and covered up by trick, scheme, or device a material fact. Specifically, he was ordered by FDA to export or destroy 118 cartons of frozen Featherback fish from import shipment N08-0026008-0 that contained *Salmonella* bacteria, with verification of such exportation or destruction by FDA. Mr. Ho concealed and covered up the material fact that he had improperly sold 103 cartons of the contaminated Featherback fish from import shipment N08-0026008-0 by a trick, scheme, or device in which he substituted 103 cartons of Featherback fish from other, unrelated import shipments and presented the substitute cartons of fish to FDA for verified exportation or destruction as the contaminated fish from import shipment N08-0026008-0.

Between on or about January 17, 2004, and September 16, 2004, in violation of 21 U.S.C. 331(c), 333(a)(1), and 342(a)(3), Mr. Ho received in interstate commerce and delivered in exchange for payment an adulterated food, namely, frozen Featherback fish from import shipment N08-0026008-0 that was contaminated with *Salmonella* bacteria.

As a result of his conviction, on June 10, 2010, FDA sent Mr. Ho a notice by certified mail proposing to debar him for a period of 15 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the act that Mr. Ho was convicted of three felonies under Federal law for conduct relating to the importation into the United States of an article of food, and a determination, after consideration of the factors set forth in section 306(c)(3) of the act (21 U.S.C. 335a(c)(3)), that the full periods of debarment shall run consecutively as provided by section 306(c)(2)(A)(iii) of the act (21 U.S.C. 335a(c)(2)(A)(iii)). The proposal also offered Mr. Ho 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. Mr. Ho failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(1)(C) of the act, and under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Mr. Su Van Ho has been convicted of three felonies under Federal law for conduct relating to the importation of an article of food into the United States and that the full periods of debarment shall run consecutively under section 306(c)(2) of the act (21 U.S.C. 335a(c)(2)).

As a result of the foregoing finding, Mr. Ho is debarred for a period of 15 years from importing articles of food or offering such articles for import into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Mr. Ho is a prohibited act.

Any application by Mr. Ho for termination of debarment under section 306(d)(1) of the act should be identified with Docket No. FDA-2010-N-0213 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(j).

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

Dated: August 12, 2010.

Howard R. Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR-266]

Availability of Draft Toxicological Profile

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR),