

District of Texas-Dallas Division, when the court accepted Mr. Hebert's plea of guilty and entered judgment against him for the offense of introduction of misbranded food into interstate commerce with intent to defraud and mislead, in violation of sections 301(a) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(a) and 333(a)(2)).

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the superseding indictment, filed on January 5, 2016, Mr. Hebert was a co-owner of USP Labs with primarily responsibilities over product packaging design. As contained in the factual résumé submitted as part of Mr. Hebert's plea agreement on March 11, 2019, and the factual resumes submitted as part of plea agreements with his codefendants, one of Mr. Hebert's codefendants instructed a Chinese company to have 2 metric tons of ground cynanchum auriculatum root powder shipped internationally to S.K. Laboratories in California for inclusion in USP Labs' dietary supplement products, using the false name "cynanchum auriculatum root extract." USP Labs sent false labels to retailers and wholesalers listing "cynanchum auriculatum (root) extract" as an ingredient in OxyElite Pro "Advanced Formula" (which went on sale in or around August 2013), even though that ingredient was not present in the product. Beginning in or around August 2013, Mr. Hebert, USP Labs, and others working at USP Labs and S.K. Laboratories, did knowingly, and with the intent to defraud and mislead, cause the shipment of a misbranded food, namely the OxyElite Pro "Advanced Formula" dietary supplement, in interstate commerce. Specifically, on or about October 4, 2013, with intent to defraud and mislead, Mr. Hebert caused the shipment of misbranded OxyElite Pro "Advanced Formula" in interstate commerce. The labeling for OxyElite Pro "Advanced Formula" falsely declared cynanchum auriculatum (root) extract as an ingredient, when in fact OxyElite Pro "Advanced Formula" contained imported cynanchum auriculatum powder but no cynanchum auriculatum (root) extract.

As a result of this conviction, FDA sent Mr. Hebert, by certified mail on March 29, 2021, a notice proposing to debar him for a period of 5 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 FD&C Act that Mr. Hebert's felony conviction of "introduction of

misbranded food into interstate commerce with intent to defraud and mislead" in violation of sections 301(a) and 303(a)(2) of the FD&C Act constitutes conduct relating to the importation into the United States of an article of food because Mr. Hebert caused the shipment of a misbranded food in interstate commerce, and the food was misbranded because its labeling falsely declared cynanchum auriculatum (root) extract as an ingredient, when in fact the imported ingredient was cynanchum auriculatum powder, not cynanchum auriculatum root extract.

The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Hebert should be subject to a 5-year period of debarment. The proposal also offered Mr. Hebert an opportunity to request a hearing, providing Mr. Hebert 30 days from the date of receipt of the letter in which to file the request, and advised Mr. Hebert that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Hebert 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 Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Matthew Hebert has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 5 year period of debarment.

As a result of the foregoing finding, Mr. Hebert is debarred for a period of 5 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 FD&C Act, 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 Matthew Hebert is a prohibited act.

Any application by Mr. Hebert for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2020-N-2340 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in

these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: July 23, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of a Supplemental Award to the University of Arkansas System Telehealth Focused Rural Health Research Center

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA announces a supplemental award in the amount of \$100,000 annually through fiscal year 2024. This funding will support the University of Arkansas Telehealth Focused Rural Health Research Center (TF RHRC), a current HRSA-funded cooperative agreement. The supplemental request is for the remaining period of performance of the current cooperative agreement, subject to the availability of funds and successful performance of the activities in a given budget year.

FOR FURTHER INFORMATION CONTACT: For further information regarding this request, please contact Nicole Hewitt, (nhewitt@hrsa.gov), (301) 443-3893.

SUPPLEMENTARY INFORMATION:

Intended Recipient of Award: University of Arkansas System.

Amount of Award Increase Non-Competitive Award: \$100,000 annually.
Period of Supplemental Funding: 9/1/2021-08/31/2024.

CFDA Number: 93.155.

Authority: Section 711(b)(5) of the Social Security Act (42 U.S.C. 912(b)(5)).

Justification: The TF RHRC program is authorized by Section 711(b)(5) of the Social Security Act (42 U.S.C. 912(b)(5)), as amended. This program is within HRSA's Federal Office of Rural Health Policy's (FORHP) Office for the Advancement of Telehealth (OAT), which administers grants, cooperative

agreements, and contracts to provide technical assistance and other activities as necessary to support activities related to improving health care in rural areas. Such activities include the evaluation of telehealth programs in rural and underserved areas.

Under the TF RHRC Program, one of the two research centers was selected to receive supplemental funding to evaluate all of OAT's programs. The University of Arkansas was awarded a cooperative agreement on September 1, 2020, to conduct evaluation-focused research and maintain a thorough and comprehensive evaluation of nationwide telehealth investments in rural areas and populations.

The University of Arkansas is presently in the first year of evaluating OAT's programs, and the current research is evaluating the impact of investments in telehealth services funded by the FORHP. In Year 1 of the grant, they have been working on evaluating OAT's Licensure and Portability Program and the Telehealth

Resource Centers. All program evaluation research falls under the jurisdiction of the University of Arkansas.

Consistent with fiscal year 2021 Departmental appropriations language, HRSA's FORHP has funded telehealth research that impacts rural areas and underserved rural populations. In addition, per the Consolidated Appropriations Act, 2021 (Pub. L. 116-260), the HHS Secretary is required to develop a strategic plan to research and evaluate the evidence for such technology-enabled collaborative learning and capacity building models.¹

As part of that directive, FORHP intends to work in consultation with the University of Arkansas who can evaluate the Telehealth Technology Enabled Learning Program (TTELP). TTELP connects specialists at academic medical centers with primary care providers in rural, frontier, and underserved populations providing evidence-based training and support to help them treat patients with complex

conditions in their communities. TTELP is also tasked with developing appropriate methodologies to evaluate and identify outcomes associated with learning community model initiatives.

The proposed activities for the supplemental funding are within the scope of the University of Arkansas' current TF RHRC cooperative agreement. This funding will allow HRSA to demonstrate whether or not this congressionally mandated program was effective. The University of Arkansas will be asked to submit a Request for Information and include a work plan, budget and budget narrative for the funding increase that incorporates this new TTELP evaluation project.

The supplemental funds are being requested for the remaining years of the cooperative agreement, subject to the availability of funds. The supplemental funds will be awarded prior to the end of the current fiscal year. The cooperative agreement ends on August 31, 2024.

Grantee/organization name	Grant number	State	FY 2021 authorized funding level	FY 2021 estimated supplemental funding
University of Arkansas for Medical Sciences	U3GRH40001	AR	\$950,000	\$100,000

Grantee/organization name	Grant number	State	FY 2022 authorized funding level	FY 2022 estimated supplemental funding
University of Arkansas for Medical Sciences	U3GRH40001	AR	\$950,000	\$100,000

Grantee/organization name	Grant number	State	FY 2023 authorized funding level	FY 2023 estimated supplemental funding
University of Arkansas for Medical Sciences	U3GRH40001	AR	\$950,000	\$100,000

Diana Espinosa,
Acting Administrator.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Community Health Aide Program: Tribal Planning & Implementation

Announcement Type: New.
Funding Announcement Number: HHS-2021-IHS-TPI-0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.382.

Key Dates

Application Deadline Date: September 1, 2021.

Earliest Anticipated Start Date: September 30, 2021.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for grants for the Community Health Aide Program (CHAP) Tribal Planning and

Implementation (TPI) program. The CHAP is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and the Indian Health Care Improvement Act, 25 U.S.C. 16161. This grant program is described in the Assistance Listings located at <https://beta.sam.gov> (formerly known as Catalog of Federal Domestic Assistance) under 93.382.

Background

The national CHAP will provide a network of health aides trained to support licensed health professionals while providing direct health care,

¹ Consolidated Appropriations Act, 2021. <https://docs.house.gov/billsthisweek/20201221/BILLS-116HR133SA-RCP-116-68.pdf> (pages 2102-2106).