Dated: May 11, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

[OMB No. 0985–0048]

Agency Information Collection Activities; Proposed Collection; Public Comment Request; State Grants for Assistive Technology Program State Plan for Assistive Technology; [OMB# 0985–0048]

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to the proposed renewal for the information collection requirements related to State Grants for Assistive Technology Program State Plan for Assistive Technology.

DATES: Submit written comments on the collection of information by June 14, 2021.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.*

Find the information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Robert Groenendaal, Assistive Technology Program Manager, Center for Innovation and Partnership in the Office of Interagency Innovation Administration for Community Living, 330 C Street SW, Washington, DC 20201, Phone: 202–795–7356, Email: *Robert.Groenendaal@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. ACL is requesting approval for the renewal of a data collection associated with the State Grants for Assistive Technology Program, State Plan for Assistive Technology.

The information collected through this data collection instrument is necessary for ACL and states to comply with Sections 4 and 7 of the Assistive Technology Act of 1998, as amended (AT Act). ACL is requesting a renewal of the state plan data collection instrument (OMB No. 0985–0048). Section 4 of the AT Act authorizes grants to public agencies in the 50 states and the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Marianas (states and outlying areas). With these funds, the 56 states and outlying areas operate ''Statewide AT Programs'' that conduct activities to increase access to and acquisition of assistive technology (AT) for individuals with disabilities and older Americans.

Divided into two comprehensive activity categories: ''State-level Activities'' and ''State Leadership Activities,'' according to Section 4 of the AT Act, as a condition of receiving a grant to support their Statewide AT Programs, the 56 states and outlying areas must provide to ACL: (1) Applications and (2) annual progress reports on their activities.

Applications: The application required of states and outlying areas is a three-year State Plan for Assistive Technology (State Plan for AT or State Plan) (OMB No. 0985–0048). The content of the State Plan for AT is based on the requirements in Section 4(d) of the AT Act.

Annual Reports: In addition to submitting a State Plan, every three years, states and outlying areas are required to submit annual progress reports on their activities. The data required in that progress report is specified in Section 4(f) of the AT Act (OMB No. 0985–0042).

National aggregation of data related to conducting required state-level and state leadership activities is necessary for the Government Performance and Results Modernization Act of 2010 (GPRAMA) (Pub. L. 111–352), as well as an Annual Report to Congress (see ''Section 7 Requirements Necessitating Collection'' below). Therefore, this data collection instrument provides a way for all 56 grantees—50 U.S. states, DC, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands to collect and report data on their activities in a consistent manner, including a uniform survey to be given to consumers. This uniform survey is included as part of the Assistive Technology Annual Performance Report (APR) data collection package (OMB No. 0985–0042).

Section 7(d) of the AT Act requires that ACL submit to Congress an annual report on the activities conducted under the Act and an analysis of the progress of the states and outlying areas in meeting measurable goals. This report must include a compilation and summary of the data collected under Section 4(f). In order to make this possible, states and outlying areas must provide their data uniformly. This data collection instrument was developed to ensure that all 56 states and outlying areas report data in a consistent manner in alignment with the requirements of Section 4(f).

As stated above, ACL will use the information collected via this instrument to:

(1) Complete the annual report to Congress required by the AT Act;

(2) Comply with reporting requirements under the Government Performance and Results Modernization Act of 2010 (GPRAMA) (Pub. L. 111–352); and

(3) Assess the progress of states and outlying areas regarding measurable goals.

Data collected from the grantees will provide a national description of activities funded under the AT Act to increase the access to and acquisition of AT devices and services through statewide AT programs for individuals with disabilities. Data collected from grantees will also provide information for usage by Congress, the Department, and the public. In addition, ACL will use this data to inform program management, monitoring, and technical assistance efforts. States will be able to use the data for internal management and program improvement.

Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register** on February 25, 2021 in FR 86 pg. 11545–11546. There were no public comments received during the 60-day FRN comment period.

Estimated Program Burden: ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
State Plan for Assistive Technology	56	1	73.0	4,088

Dated: May 11, 2021.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2047]

Rick Shepard: Final 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 (FD&C Act) debarring Rick Shepard for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Shepard was convicted of one felony count under Federal law for conspiracy to import and introduce misbranded drugs into interstate commerce. The factual basis supporting Mr. Shepard's conviction is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Shepard was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of February 14, 2021 (30 days after receipt of the notice), Mr. Shepard had not responded. His failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable May 14, 2021.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa (ELEM–4029), Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if the FDA finds, as required by section 306(b)(3)(C) of the FD&C, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance. On September 14, 2020, Mr. Shepard was convicted, as defined in section 306(*l*)(1) of the FD&C Act, in the U.S. District Court for the District of Kansas, when the court entered judgment against him for the offense of ''Conspiracy to Import and Introducing Misbranded Drugs into Interstate Commerce, a Class D Felony'' in violation of 18 U.S.C. 371.

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Plea Agreement in Mr. Shepard's case, filed on January 27, 2020, Mr. Shepard owned, controlled, and operated Epic Products, LLC (Epic), a Kansas Limited Liability Company, from approximately October 2013 until at least April 2018. Epic was engaged in wholesaling of products under the labeled name ''Euphoric'' that were marketed as ''all-natural, herbal supplements for male enhancement.'' Euphoric's label made no mention of tadalafil and sildenafil citrate. However, Mr. Shepard knew that Euphoric contained tadalafil and sildenafil citrate because he imported these drugs, repacked them, and sold them under the Euphoric label. Specifically, Mr. Shepard purchased in bulk from suppliers in China capsules containing tadalafil and sildenafil citrate that he had delivered to mail and packing stores on the east coast before forwarding them to his address in Kansas.

Sildenafil citrate is the active ingredient in Pfizer, Inc.'s FDA-approved erectile dysfunction drug, VIAGRA. Likewise, tadalafil is the active ingredient in Eli Lilly & Company's FDA-approved erectile dysfunction drug, CIALIS. Once Mr. Shepard received the bulk capsules, he repackaged them and applied his Euphoric label. Mr. Shepard then sold these capsules in novelty stores in Kansas, Missouri, and Colorado. Throughout this entire scheme, Mr. Shepard did not possess a valid wholesale drug distribution license, a valid pharmacy license, or a license to prescribe prescription drugs. Finally, from January 2012 to September 2017, Mr. Shepard deposited $1.8 million into his business account.

As a result of this conviction, FDA sent Mr. Shepard, by certified mail on December 21, 2020, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding, under section 306(b)(3)(C) of the FD&C Act, that Mr. Shepard's felony conviction for one felony count under Federal law, for the offense of ''Conspiracy to Import And Introducing Misbranded Drugs into Interstate Commerce, a Class D Felony,'' was for conduct relating to the importation into the United States of any drug or controlled substance because he illegally imported, repackaged, and introduced misbranded tadalafil and sildenafil capsules into interstate commerce.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Shepard's offense and concluded that this felony offense warranted the imposition of a 5-year period of debarment. The proposal informed Mr. Shepard of the proposed debarment and offered him 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. Shepard received the proposal and notice of opportunity for a hearing on January 15, 2021. He failed to request a hearing 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