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.

[FR Doc. 2021–10239 Filed 5–13–21; 8:45 am]

BILLING CODE 4154–01–P

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

306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Rick Shepard has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Shepard is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Mr. Shepard is a prohibited act.

Any application by Mr. Shepard for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2020–N–2047 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: May 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10249 Filed 5–13–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0008]

Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on June 3 and 4, 2021, from 9 a.m. Eastern Time to 6 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, *james.swink@fda.hhs.gov,* 301–796–6313, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website *https://www.fda.gov/advisory-committees/medical-devices/medical-devices-advisory-committee* and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On June 3, 2021, during session I, the committee will discuss and make recommendations regarding the classification of topical refrigerants (vapocoolants), which are currently unclassified preamendment devices, to class II (general and special controls). During session II, the committee will discuss and make recommendations regarding the classification of acupressure devices, which are currently unclassified preamendment devices, to class I (general controls). During session III, the committee will discuss and make recommendations regarding the classification of electro-acupuncture stimulators, which are currently unclassified preamendment devices, to class II (general and special controls).

On June 4, 2021, during session I, the committee will discuss and make recommendations regarding the classification of attention task performance recorders, which are currently unclassified preamendment devices, to class II (general and special controls). During session II, the committee will discuss and make recommendations regarding the classification of optical contour sensing devices, which are currently unclassified preamendment devices, to class I (general controls). During session III, the committee will discuss and make recommendations regarding the classification of plunger-like joint manipulators, which are currently unclassified preamendment devices, to class II (general and special controls).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/advisory-committees/medical-devices/medical-devices-advisory-committee.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 21, 2021. Oral presentations from the public will be scheduled on June 3 and June 4, 2021, between approximately 9:15 a.m. and 10:15 a.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 13, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will