territories and the state/territory offices that oversee early care and education. The results of this study also have implications for child care programs and staff. Further, given the U.S. Congress' interest in prior exploratory work on this topic, it may be informative for federal lawmakers, as well.

CCDF lead agency staff and CAN registry custodians that participate in this information collection will be asked to complete a voluntary, one-time web-based survey. The survey for CCDF lead agency staff will focus on the practices and policies related both to in-state/territory and interstate CAN registry checks, including what data they request and receive, as well as how they use it in making child care employment eligibility decisions. The survey for CAN registry custodians will focus on the contents of CAN registries, policies around inclusion in/expunction from the registries, and policies regarding sharing data.

Approximately half of CCDF lead agency survey respondents (up to 28) will be invited to participate in voluntary follow-up interviews. This open-ended data collection format will allow for exploration of key themes that emerge from the surveys; facilitators and barriers in, and respondent recommendations around, implementing the CAN registry checks; how practice may vary from policy; and, in some cases, to obtain answers to questions not answered in the survey.

Respondents: Each state, territory, and the District of Columbia will be invited to complete two web-based surveys: one CCDF lead agency survey and one CAN registry custodian survey. Given that each agency may have multiple staff members with relevant knowledge of different survey topics and no one staff member may possess all of the knowledge to complete the survey, we are allowing for up to 3 respondents per state/territory for the CCDF lead agency staff and 2 respondents per state/territory for the CAN registry custodian surveys (up to 280 total individuals). Once survey administration is complete, one CCDF lead agency staff person from half of the states, territories, and the District of Columbia (up to 28) will be invited to participate in a follow-up interview. For the interviews, we will select a sample of CCDF lead agency staff that represents diversity across state and territory approaches toward the CAN registry background checks.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
Instrument 1: CCDF Lead Agency Survey	168	1	*0.75	126
Instrument 2: CAN Custodian Survey	112	1	*0.75	84
Instrument 3: CCDF Lead Agency Interview	28	1	1.50	42
Estimated Total Annual Burden Hours:				252

*Note that this is the estimated time to complete the full survey, which could be completed by one individual or multiple individuals. Surveys completed by multiple individuals will take less time for each individual to provide a response.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Research funding set-aside authorized by the CCDBG Act of 2014 and funded by CCDF. Section 658O(a)(5) of CCDBG (as codified at 42 U.S.C. 9857 *et seq.*) grants the Secretary of the U.S. Department of Health and Human Services the authority to reserve up to ½ percent of the total Discretionary and Mandatory CCDF funding ''to conduct research and demonstration activities, as well as periodic external, independent evaluations of the impact of the program described by this subchapter on increasing access to child care services and improving the safety and quality of child care services, using scientifically valid research methodologies, and to disseminate the key findings of those evaluations widely and on a timely basis.''

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–17435 Filed 8–14–23; 8:45 am]

BILLING CODE 4184–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0250]

Ildiko M. Knoll: 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 Ildiko M. Knoll 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 Ms. Knoll engaged in a pattern of importing or offering for import misbranded drugs (*i.e.,* in an amount, frequency, or dosage that is inconsistent with personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. Ms. Knoll was given notice of the proposed debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of May 29, 2023 (30 days after receipt of the notice), Ms. Knoll had not responded. Ms. Knoll's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this matter.

DATES: This order is applicable August 15, 2023.

ADDRESSES: Any application by Ms. Knoll for termination of debarment

under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2023–N–0250. Received applications will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 240–402–8743, or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(D) of the FD&C Act, that the individual has engaged in a pattern of importing or offering for import (*i.e.,* in an amount, frequency, or dosage that is inconsistent with personal or household use) misbranded drugs that are not designated in an authorized electronic data interchange system as products regulated by FDA.

After an investigation, FDA discovered that Ms. Knoll had engaged in numerous instances of importing or offering for import misbranded drugs. Specifically, between November 24, 2021, and November 29, 2022, Ms. Knoll imported or offered for import 100 parcels containing a total of 100 products (18,435 pieces, 9,495 tablets) that contained tadalafil and sildenafil. FDA determined that these products were misbranded drugs because their labeling lacked adequate directions for use, as required by section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and/or they were prescription drugs and their labels failed to bear the symbol ''Rx only,'' as required by section 503(b)(4)(A) of the FD&C Act (21 U.S.C. 353(b)(4)(A)). All the parcels containing the misbranded drugs serving as the basis for this action were intercepted by FDA at the John F. Kennedy International Mail Facility and were addressed to Ms. Knoll at an address connected to her.

As a result of this pattern of importing or offering for import (*i.e.* in an amount, frequency, or dosage that is inconsistent with personal or household use) misbranded drugs that are not designated in an authorized electronic data interchange system as products regulated by FDA, in accordance with section 306(b)(3)(D) of the FD&C Act, FDA sent Ms. Knoll, by United Parcel Service on April 27, 2023, a notice proposing to debar her for a 5-year period from importing or offering for import any drug into the United States. The attachment to that notice contained a table listing all the parcels intercepted by FDA that contained the misbranded drugs serving as a basis for this action. Among other pieces of information, that table contained the submission date of the entry, the product contained in the package, the quantity of the product, and the product violation FDA found for each entry. That attachment is posted to the docket and can be accessed by the public at *https://www.regulations.gov.* 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 Ms. Knoll's pattern of conduct and concluded that her conduct warranted the imposition of a 5-year period of debarment. The proposal informed Ms. Knoll of the proposed debarment and offered her an opportunity to request a hearing, providing 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Knoll received the proposal and notice of opportunity for a hearing on April 29, 2023. Ms. Knoll failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her 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)(D) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Knoll has engaged in a pattern of importing or offering for import (*i.e.* in an amount, frequency, or dosage that is inconsistent with personal or household use) misbranded drugs that are not designated in an authorized electronic data interchange system as products regulated by FDA. FDA finds that this pattern of conduct 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, Ms. Knoll 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 by, with the assistance of, or at the direction of Ms. Knoll is a prohibited act.

Dated: August 9, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17481 Filed 8–14–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0745]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biologics License Applications Procedures and Requirements; Voluntary Consensus Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 14, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0338. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Biologics License Applications (BLAs) Procedures and Requirements

OMB Control Number 0910–0338—Revision

This information collection helps support FDA implementation of statutory and regulatory requirements that govern biologics product licensing. We have issued regulations in 21 CFR parts 600–680 setting forth applicable standards and procedures that include associated reporting, recordkeeping, and disclosure requirements. Respondents to the information collection are persons or entities who engage in manufacture of biologics products. We provide information on our website at *https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber* regarding BLAs, including available Agency resources.

We are revising the information collection to support implementation of a standards recognition program for regenerative medicine therapies at FDA's Center for Biologics Evaluation and Research (CBER) designed to identify and recognize Voluntary Consensus Standards (VCS) to facilitate the development and assessment of regenerative medicine therapy (RMT) products regulated by CBER when such standards are appropriate. The draft guidance for industry entitled ''Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies'' (June 2022) describes procedures CBER will follow when a request for recognition of a VCS is received. The draft guidance also explains that any interested party may request recognition of a VCS. The draft guidance document is available for download at *https://www.fda.gov/media/159237/download.* We issued the guidance document consistent with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. We intend on finalizing the guidance document upon OMB approval of the attendant information collection.

The use of recognized VCS can assist stakeholders in more efficiently meeting regulatory requirements and increasing regulatory predictability for RMT products. We will use requests for recognition to help identify appropriate VCS that facilitate the development and assessment of RMT products. We encourage sponsors to use FDA-recognized VCS in submissions, as conformity to relevant standards helps streamline regulatory review, foster quality, and may facilitate a manufacturer's preparation of submissions. As explained in Section V of the draft guidance document, any stakeholder can request recognition of a specific VCS.

In the **Federal Register** of June 16, 2022 (87 FR 36327), we published a 60-day notice announcing the availability of the draft guidance and invited public comment on the proposed collection of information. We received comment letters supportive of our use of voluntary consensus standards for regenerative medicine therapies. Comments encouraged broad application of a voluntary consensus program. No comments were received regarding the request for recognition information collection provisions and FDA's need for the information; the accuracy of our burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected in the requests; or ways to minimize burden of the requests. Comments are being considered as the guidance is finalized.

Description of Respondents: Respondents to this collection of information are product sponsors, applicants and other stakeholders interested in the development of RMT products regulated in CBER.

We estimate the burden of this collection of information as follows: