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:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Voluntary consensus standards recognition program for regenerative medicine therapies; guidance for industry	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Request for recognition of a voluntary consensus standard and submission of information as specified in Section V	9	1	9	3	27

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate is based on our experience with similar information collection activities. We note that standards development can be a lengthy process and provide an estimate we believe reflects the amount of time necessary to prepare and submit the information as discussed in Section V of the guidance document.

Dated: August 9, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17460 Filed 8–14–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3007]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Human Drug Compounding Outsourcing Facilities Under the Federal Food, Drug, and Cosmetic Act and Associated Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection pertaining to the registration of human drug compounding outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and associated fees.

DATES: Either electronic or written comments on the collection of information must be submitted by October 16, 2023

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 16, 2023 Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *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 written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–3007 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act and Associated Fees Under Section 744K.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 comments. 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 to read background documents or the