(21 CFR part 203), Prescription Drug Marketing.

The regulations in part 203 include reporting and recordkeeping requirements intended to help achieve the following goals to: (1) ban the reimportation of prescription drugs produced in the United States, except when reimported by the manufacturer or under FDA authorization for emergency medical care; (2) ban the sale, purchase, or trade, or the offer to sell, purchase, or trade, of any prescription drug sample; (3) limit the distribution of drug samples to practitioners licensed or authorized to prescribe such drugs or to pharmacies of hospitals or other healthcare entities at the request of a licensed or authorized practitioner; (4) require licensed or authorized practitioners to request prescription drug samples in writing; (5) mandate storage, handling, and recordkeeping requirements for prescription drug samples; and (6) prohibit, with certain exceptions, the sale, purchase, or trade, or the offer to sell, purchase, or trade, of prescription drugs that were purchased by hospitals or other healthcare entities or that were donated or supplied at a reduced price to a charitable organization.

Respondents: Respondents to the information collection are persons or entities engaged in prescription drug marketing.

In the **Federal Register** of January 22, 2024 (89 FR 3928), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four information collection topics solicited in our 60-day notice.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 203.11; Reimportation	1	1	1	0.5 (30 minutes)	0.5
§ 203.37(a); Falsification of records	140	2.14	300	0.25 (15 minutes)	75
§ 203.37(b); Loss or theft of samples	140	57.14	8,000	0.25 (15 minutes)	2,000
§ 203.37(c); Convictions	1	1	1	1	1
§ 203.37(d); Contact person	20	1	20	0.08 (5 minutes)	2
§ 203.39(g); Reconciliation report	1	1	1	1	1
Total			8,323		2,080

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Subpart C: Sale restrictions					
§ 203.23(a) and (b); Returned drugs	2,200	71.99	158,380	0.25 (15 minutes)	39,595
§ 203.23(c); Returned drugs storage documentation	2,200	71.99	158,380	0.08 (5 minutes)	12,670
Subpart D: Samples					
§§ 203.30 to 203.39; documentation regarding sample distribution	140	46,716.67	6,540,334	0.08 (5 minutes)	523,227
Total			6,857,094		575,492

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

Based on a review of Agency data, since our last request for OMB approval, cumulatively our estimate reflects an increase of 6,492,354 responses and 516,028 hours annually. The estimates in table 1 reflect an assessment of the volume of loss/theft/falsification reports received by the Agency under § 203.37 over the past 18 months. While the requirements have not changed, we believe the current figures more accurately reflect the number of reports estimated to be submitted to FDA under this section. Our adjustments to table 2 are attributable to a more accurate reflection of the number of drug sample requests received by manufacturers and authorized distributors of record. The PDMA does not require manufacturers and distributors to report the number of drug sample requests they receive to FDA. However, section 6004 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) requires that manufacturers and authorized distributors submit to FDA annually the identity and quantity of drug samples requested, among other information.

Dated: May 31, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–12357 Filed 6–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5324]

Marina Sievert: 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 Marina Sievert for a period of 10 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Ms. Sievert was convicted of one felony count under Federal law for mail fraud and one felony count under Federal law

for introduction of an unapproved new drug into interstate commerce. The factual basis supporting Ms. Sievert's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Ms. Sievert 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 March 10, 2024 (30 days after receipt of the notice), Ms. Sievert had not responded. Ms. Sievert'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 June 6, 2024.

ADDRESSES: Any application by Ms. Sievert for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time 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–5324. 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. 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, at 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)(C) of the FD&C Act, 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 October 31, 2023, Ms. Sievert was convicted as defined in section 306(l)(1) of the FD&C Act in the United States District Court for the Middle District of Florida-Tampa Division when the court accepted her plea of guilty and entered judgment against her for two felony offenses, mail fraud in violation of 18 U.S.C. 1341 and introduction of an unapproved new drug into interstate commerce in violation of 21 U.S.C. 331(d), 355(a), and 333(a)(2). The underlying facts supporting the conviction are as follows: as contained in the Indictment and the Plea Agreement from her case, beginning in or about July 2019, and continuing through in or about April 2022, Ms. Sievert served as the registered agent, president, and director of Beauty Forever Florida, Inc. (BFF). In addition, Ms. Sievert operated the website *www.beautyforeverflorida.com* (the BFF website) on behalf of BFF. Through the BFF website Ms. Sievert sold a variety of foreign unapproved beauty and skin care products, including botulinum toxin type A drugs, to customers across the United States. On BFF's website Ms. Sievert promoted and sold a Korean pharmaceutical company's products, Innotox Medytox and Meditoxin. Innotox Medytox and Meditoxin were injectable botulinum toxin type A products that Ms. Sievert advertised would temporarily improve moderate to severe wrinkle lines and/or procerus muscle activity in adults. FDA-approved drug products containing botulinum toxin type A are only available pursuant to a prescription from a licensed prescriber. Innotox Medytox and Meditoxin lacked required FDA approval and were unapproved new drugs. Ms. Sievert ordered, purchased, imported, and received Innotox Medytox and Meditoxin from a foreign pharmaceutical retailer for the purpose of redistributing them to BFF's customers in the United States. The BFF website's online store used false and fraudulent pretenses and representations, including false and misleading claims that BFF's products were ''FDA approved,'' had ''cleared customs,'' and had ''guaranteed authenticity.''

On or about March 13, 2020, FDA agents advised Ms. Sievert that receiving foreign unapproved new drugs, including specifically foreign toxins, in interstate commerce and delivering or offering to deliver those drugs to others was a violation of Federal law. FDA agents warned Ms. Sievert that the foreign unapproved new

drugs that she was selling online through the BFF website were not ''FDA approved.'' Despite these warnings, Ms. Sievert continued operating BFF and the BFF website in the same manner as she had prior to the FDA's warnings.

On or about March 29, 2021, an FDA Office of Criminal Investigations agent conducted an online undercover purchase from the BFF website. The agent purchased five units of injectable botulinum type A labeled as ''Innotox 100U. Korea'' and five units of injectable botulinum type A labeled as ''Meditoxin 200U-Botulinum A Toxin.'' On or about March 30, 2021, the agent received the undercover purchase made from the BFF website. The ''Innotox Medytox'' and ''Meditoxin'' labeled products were tested by FDA. Both products tested positive for the presence of botulinum toxin type A. Between July 2019 and April 2022 Ms. Sievert derived more than $1,500,000 from her illegal sales of foreign unapproved new drugs.

FDA sent Ms. Sievert, by certified mail, on November 30, 2023, a notice proposing to debar her for a 10-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 Ms. Sievert's felony convictions under Federal law for mail fraud in violation of 18 U.S.C. 1341 and introduction of an unapproved new drug into interstate commerce in violation of 21 U.S.C. 331(d), 355(a), and 333(a)(2) was for conduct relating to the importation into the United States of any drug or controlled substance because Ms. Sievert illegally imported unapproved new drugs containing botulinum toxin type A and sold those products to her company's customers throughout the United States. 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. Sievert's offenses and concluded that the offenses warranted the imposition of a 10-year period of debarment.

The proposal informed Ms. Sievert of the proposed debarment and offered her an opportunity to request a hearing, providing her 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. Sievert received the proposal and notice of opportunity for a hearing on February 9, 2024. Ms. Sievert 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)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Marina Sievert has been convicted of two felonies under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offenses should each be accorded a debarment period of 5 years, to run consecutively for a total debarment period of 10 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Ms. Sievert is debarred for a period of 10 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. Sievert is a prohibited act.

Dated: May 31, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–12356 Filed 6–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5746]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Record Retention Requirements for the Soy Protein and Reduced Risk of Coronary Heart Disease Health Claim

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 July 8, 2024.

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 0910–0428. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Record Retention Requirements for the Soy Protein and Reduced Risk of Coronary Heart Disease Health Claim—21 CFR 101.82

OMB Control Number 0910–0428—Extension

Section 403(r)(3)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(3)(A)) provides for the use of food label statements characterizing a relationship of any nutrient of the type required to be in the label or labeling of the food to a disease or a health-related condition only where that statement meets the requirements of the regulations issued by the Secretary of Health and Human Services to authorize the use of such a health claim. Section 101.82 (21 CFR 101.82) of our regulations authorizes a health claim for food labels about soy protein and the risk of CHD. Accordingly, we established this information collection in support of the regulation.

This information collection enables us to review food labeling ingredient information to determine the basis of soy protein/CHD health claims. Respondents are required to retain records for FDA inspection regarding calculation of the ratio of soy protein to total protein in a food when that food bears a soy protein/CHD health claim.

While we are currently proposing to revoke the regulation (RIN 0910–AH43) as announced in the **Federal Register** of October 31, 2017 (82 FR 50324), the regulation remains in effect. Once we finalize the proposed rule, the associated information collection