

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.*

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## 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](mailto: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

requirements under this OMB control number will be revoked. Until such time and in accordance with the PRA, we retain our currently approved burden estimate for this information collection.

*Description of Respondents:*  
Respondents include businesses engaged in the manufacture of foods

containing soy and other proteins that bear soy protein/CHD health claims. Respondents to the information collection are from the private sector (for-profit businesses).

In the **Federal Register** of January 23, 2024 (89 FR 4309), FDA published a 60-day notice requesting public comment

on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
101.82; Soy protein/CHD health claim .....	25	1	25	1	25

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The records currently required to be retained under § 101.82(c)(2)(ii)(B) are the records, e.g., the formulation or recipe, that a manufacturer has and maintains as a normal course of its doing business. Thus, the burden to the food manufacturer is limited to assembling and retaining the records.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: May 31, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–12359 Filed 6–5–24; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Announcement of the President’s Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders Meeting and Solicitation for Oral and Written Comments**

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of Intergovernmental and External Affairs, White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders.

**ACTION:** Notice of meeting and solicitation for written and oral comments.

**SUMMARY:** The U.S. Department of Health and Human Services (HHS) announces the ninth public meeting of the President’s Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders (Commission) and the solicitation of written and oral comment regarding the advancement of equity, justice, and opportunity for Asian American, Native Hawaiian, and Pacific Islander (AA and NHPI) communities. The meeting is open to

the public and will be held in Saint Paul, Minnesota. Virtual attendance will be available through livestream on July 1 and in-person attendance will be available on July 2, 2024. The Commission is working to accomplish its mission to provide independent advice and recommendations to the President on ways to advance equity, justice, and opportunity for AA and NHPI communities.

**DATES:** The Commission will meet on July 1, 2024, from 11:00 a.m. Eastern Time (ET) to 5:00 p.m. ET and July 2, 2024, from 2:00 p.m. ET to 6:00 p.m. ET. The final location and agenda will be posted on the website for the President’s Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders: <https://www.hhs.gov/about/whiaanhpi/commission/index.html> when this information becomes available.

**ADDRESSES:** Members of the public may attend the meeting virtually or in person, depending on the portion of the meeting. Registration is required through the following links:

*July 1 meeting (virtual attendance only):* <https://www.eventbrite.com/e/meeting-of-the-presidents-advisory-commission-on-aa-and-nhpi-tickets-911468415567?aff=oddtcreator>  
*July 2 public listening session (in-person attendance only):* <https://www.eventbrite.com/e/presidents-advisory-commission-on-aa-and-nhpi-listening-session-tickets-911482939007?aff=oddtcreator>

**FOR FURTHER INFORMATION CONTACT:** Judith Teruya, Lead Designated Federal Officer, President’s Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders, U.S. Department of Health and Human Services, Office of the Secretary, Office of Intergovernmental and External Affairs, U.S. Department of Health and Human Services, Hubert Humphrey Building, 620E, 200 Independence Ave.

SW, Washington, DC 20201; email: [AANHPICommission@hhs.gov](mailto:AANHPICommission@hhs.gov); telephone: (202) 951–0235.

**SUPPLEMENTARY INFORMATION:**

*Background:* The meeting is the ninth in a series of federal advisory committee meetings regarding the development of recommendations to advance equity, justice, and opportunity for AA and NHPI communities. The meeting is open to the public and will be live streamed. The Commission, co-chaired by U.S. Health and Human Services Secretary Xavier Becerra and the U.S. Trade Representative Ambassador Katherine Tai, advises the President on: the development, monitoring, and coordination of executive branch efforts to advance equity, justice, and opportunity for AA and NHPI communities in the United States, including efforts to close gaps in health, socioeconomic, employment, and educational outcomes; policies to address and end anti-Asian bias, xenophobia, racism, and nativism, and opportunities for the executive branch to advance inclusion, belonging, and public awareness of the diversity and accomplishments of AA and NHPI people, cultures, and histories; policies, programs, and initiatives to prevent, report, respond to, and track anti-Asian hate crimes and hate incidents; ways in which the Federal Government can build on the capacity and contributions of AA and NHPI communities through equitable Federal funding, grantmaking, and employment opportunities; policies and practices to improve research and equitable data disaggregation regarding AA and NHPI communities; policies and practices to improve language access services to ensure AA and NHPI communities can access Federal programs and services; and strategies to increase public- and private-sector collaboration, and community involvement in improving the safety and socioeconomic, health, educational,