Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

FOR FURTHER INFORMATION CONTACT: Sara Camilli, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3486, Silver Spring, MD 20993–0002, 301–796–4203, *Sara.Camilli@fda.hhs.gov;* or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final document entitled ''Best Practices for FDA Staff in the Postmarketing Safety Surveillance of Human Drug and Biological Products.''

Title IX, section 915 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85) added section 505(r) to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(r)), requiring FDA to prepare a summary analysis of the adverse drug reaction reports received for a drug by 18 months after approval or after use of the drug by 10,000 individuals, whichever is later. The analysis includes identification of any new risks not previously identified, potential new risks, or known risks reported in unusual number.

Section 3075 of the Cures Act (Pub. L. 114–255) amended section 505(r)(2)(D) of the FD&C Act to eliminate the requirement for summary analyses for drugs as required by FDAAA. In place of the summary analyses, section 3075 amended section 505(r)(2)(D) of the FD&C Act to include the requirement that FDA make publicly available on its internet website best practices for drug safety surveillance activities for drugs approved under section 505 of the FD&C Act or section 351 of the Public Health Service Act (PHS Act).

Section 3075 of the Cures Act also amended section 505(k)(5) of the FD&C Act to strike ''bi-weekly screening,'' in subparagraph (A), and insert ''screenings''; it also added the requirement that FDA make publicly available on its internet website guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System.

The final document entitled ''Best Practices for FDA Staff in the Postmarketing Safety Surveillance of Human Drugs and Biological Products'' sets forth risk-based principles for FDA's conduct of ongoing postmarketing safety surveillance for human drug products and human biological products to address the Cures Act requirements. Although section 3075 of the Cures Act only references drugs approved under section 505 of the FD&C Act or section 351 of the PHS Act, the document additionally discusses other products, including nonprescription drug products, compounded drug products, and homeopathic products. The document also includes a high-level overview of other drug safety surveillance data sources, tools, methods, and activities that extend beyond use of FDA's adverse event reporting systems, as well as regulatory and other actions that can be taken in response to identified safety signals. These additional topics are included to provide context and a general overview of FDA's safety surveillance process.

This document finalizes the draft document entitled ''Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff,'' issued on November 7, 2019 (84 FR 60094). FDA considered comments received on the draft document as the document was finalized. Changes from the draft to the final document include: (1) document title revised to emphasize this document's focus on postmarketing safety surveillance and to clarify that this document only refers to human drug and biological products that are regulated by FDA, as this document does not refer to animal drugs regulated by FDA; (2) additional content to distinguish between the use of the terms *adverse event* and *adverse reaction;* (3) clarification of products that generally are subject to more extensive monitoring and types of safety information for focus; (4) addition of a description of the FDA Adverse Event Reporting System Public Dashboard; (5) revisions to the content on medication errors, for clarity; (6) revisions to the section on the pregnant population to align with the most recently issued documents pertaining to clinical trials and postapproval pregnancy safety studies; (7) inclusion of citations referencing the Sentinel System; (8) revisions to the description of the process for signal evaluation and documentation, including addition of a reference to the Center for Drug Evaluation and Research's ''Manual of Policies and Procedures for Collaborative Identification, Evaluation, and Resolution of a Newly Identified Safety Signal''; (9) inclusion of an expanded discussion of product labeling changes; and (10) additional content regarding Drug Safety Communications. Editorial changes were made to improve clarity.

II. Electronic Access

Persons with access to the internet may obtain the document at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-office-surveillance-and-epidemiology* or *https://www.regulations.gov.*

Dated: January 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01584 Filed 1–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2853]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle

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 February 26, 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 0910–0623. 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.

Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle—21 CFR 189.5 and 700.27

OMB Control No. 0910–0623—Extension

This information collection supports FDA regulations in §§ 189.5 and 700.27 (21 CFR 189.5 and 700.27) that set forth bovine spongiform encephalopathy (BSE)-related restrictions applicable to FDA-regulated human food and cosmetics. The regulations designate certain materials from cattle as ''prohibited cattle materials,'' including specified risk materials (SRMs), the small intestine of cattle not otherwise excluded from being a prohibited cattle material, material from nonambulatory disabled cattle, and mechanically separated (MS) beef. Sections 189.5(c) and 700.27(c) set forth the requirements for recordkeeping and records access for FDA-regulated human food, including dietary supplements, and cosmetics manufactured from, processed with, or otherwise containing material derived from cattle. FDA issued these recordkeeping regulations under the adulteration provisions in sections 402(a)(2)(C), (a)(3), (a)(4), (a)(5), 601(c), and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(2)(C), (a)(3), (a)(4), (a)(5), 361(c), and 371(a)). Under section 701(a) of the FD&C Act, we are authorized to issue regulations for the FD&C Act's efficient enforcement. With regard to records concerning imported human food and cosmetics, FDA relied on our authority under sections 701(b) and 801(a) of the FD&C Act (21 U.S.C. 371(b) and 381(a)). Section 801(a) of the FD&C Act provides requirements with regard to imported human food and cosmetics and provides for refusal of admission of human food and cosmetics that appear to be adulterated into the United States. Section 701(b) of the FD&C Act authorizes the Secretaries of Treasury and Health and Human Services to jointly prescribe regulations for the efficient enforcement of section 801 of the FD&C Act.

These requirements are necessary because once materials are separated from an animal it may not be possible, without records, to know the following: (1) whether cattle material may contain SRMs (brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia from animals 30 months and older and tonsils and distal ileum of the small intestine from all animals of all ages); (2) whether the source animal for cattle material was inspected and passed; (3) whether the source animal for cattle material was nonambulatory disabled, or MS beef; and (4) whether tallow in human food or cosmetics contain less than 0.15 percent insoluble impurities.

FDA's regulations in §§ 189.5(c) and 700.27(c) require manufacturers and processors of human food and cosmetics manufactured from, processed with, or otherwise containing material from cattle establish and maintain records sufficient to demonstrate that the human food or cosmetics are not manufactured from, processed with, or otherwise contain prohibited cattle materials. These records must be retained for 2 years at the manufacturing or processing establishment or at a reasonably accessible location. Maintenance of electronic records is acceptable, and electronic records are considered to be reasonably accessible if they are accessible from an onsite location. Records required by these sections and existing records relevant to compliance with these sections must be available to FDA for inspection and copying. Existing records may be used if they contain all of the required information and are retained for the required time period.

Because we do not easily have access to records maintained at foreign establishments, FDA regulations in §§ 189.5(c)(6) and 700.27(c)(6), respectively, require that when filing for entry with U.S. Customs and Border Protection, the importer of record of human food or cosmetics manufactured from, processed with, or otherwise containing, cattle material must affirm that the human food or cosmetics were manufactured from, processed with, or otherwise contains, cattle material and must affirm that the human food or cosmetics were manufactured in accordance with the applicable requirements of §§ 189.5 or 700.27. In addition, if human food or cosmetics were manufactured from, processed with, or otherwise contains cattle material, the importer of record must provide within 5 business days records sufficient to demonstrate that the human food or cosmetics were not manufactured from, processed with, or otherwise contains prohibited cattle material, if requested.

Under FDA's regulations, we may designate a country from which cattle materials inspected and passed for human consumption are not considered prohibited cattle materials, and their use does not render human food or cosmetics adulterated. Sections 189.5(e) and 700.27(e) provide that a country seeking to be designated must send a written request to the Director of the Center for Food Safety and Applied Nutrition. The information the country is required to submit includes information about a country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether SRMs, the small intestine of cattle not otherwise excluded from being a prohibited cattle material, material from nonambulatory disabled cattle, or MS beef from the country seeking designation should be considered prohibited cattle materials. We use the information to determine whether to grant a request for designation and to impose conditions if a request is granted.

Sections 189.5 and 700.27 further state that countries designated under §§ 189.5(e) and 700.27(e) will be subject to future review by FDA to determine whether their designations remain appropriate. As part of this process, we may ask designated countries to confirm their BSE situation and the information submitted by them, in support of their original application, has remained unchanged. We may revoke a country's designation if we determine that it is no longer appropriate. Therefore, designated countries may respond to periodic FDA requests by submitting information to confirm their designations remain appropriate. We use the information to ensure their designations remain appropriate.

Description of Respondents: Respondents to this information collection include manufacturers, processors, and importers of FDA-regulated human food, including dietary supplements, and cosmetics manufactured from, processed with, or otherwise containing material derived

from cattle, as well as, with regard to §§ 189.5(e) and 700.27(e), foreign governments seeking designation under those regulations.

In the **Federal Register** of August 11, 2023 (88 FR 54617), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment that was not related to the PRA and therefore will not be addressed in this document.

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
189.5(c)(6) and 700.27(c)(6); affirmation of compliance.	54,825	1	54,825	0.033 (2 minutes)	1,809
189.5(e) and 700.27(e); request for designation.	1	1	1	80	80
189.5(e) and 700.27(e); response to request for review by FDA.	1	1	1	26	26
Total					1,915

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Domestic Facilities	697	52	36,244	0.25 (15 minutes)	9,061
Foreign Facilities	916	52	47,632	0.25 (15 minutes)	11,908
Total					20,969

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

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: January 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01586 Filed 1–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6827]

Advisory Committee; Vaccines and Related Biological Products Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Vaccines and Related Biological Products Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Vaccines and Related Biological Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the December 31, 2025, expiration date.

DATES: Authority for the Vaccines and Related Biological Products Advisory Committee will expire on December 31, 2025, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Sussan Paydar, Division of Scientific Advisors and Consultants, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 202–657–8533, *Sussan.Paydar@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Vaccines and Related Biological Products Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective vaccines and related biological products for human use, and as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and as required, any other products for which FDA has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program, which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner.

Pursuant to its charter, the Committee shall consist of a core of 15 voting members, including the Chairperson (the Chair). Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of immunology, molecular biology, rDNA, virology, bacteriology, epidemiology or biostatistics, vaccine policy, vaccine safety science, federal immunization activities, vaccine development including translational and clinical evaluation programs, hypersensitivity reactions to the vaccines, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry. Members will be invited