disease through their second RSV season.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before May 24, 2023, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 16, 2023. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 17, 2023.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact She-Chia Jankowski (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09321 Filed 5–2–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1619]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

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 June 2, 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 0910–0606. 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.

Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements—21 CFR Part 111

OMB Control Number 0910–0606—Extension

The Dietary Supplement Health and Education Act (Pub. L. 103–417) added section 402(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(g)), which provides, in part, that the Secretary of Health and Human Services may, by regulation, prescribe good manufacturing practice for dietary supplements. Section 402(g) of the FD&C Act also stipulates that such regulations will be modeled after Current Good Manufacturing Practice (CGMP) regulations for food and may not impose standards for which there are no current, and generally available, analytical methodology. Section 402(g)(1) of the FD&C Act states that a dietary supplement is adulterated if it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.

Accordingly, we have issued regulations in part 111 (21 CFR part 111) establishing minimum CGMP requirements pertaining to the manufacturing, packaging, labeling, or holding of dietary supplements to ensure their quality. Included among the requirements is recordkeeping, documenting, planning, control, and improvement processes of a quality control system. Implementation of these processes in a manufacturing operation serves as the backbone to CGMP. The records must show what is being manufactured and whether the controls in place ensure the product's identity, purity, strength, and composition and that limits on contaminants and measures to prevent adulteration are effective. Further, records must show whether and what deviations from control processes occurred, facilitate evaluation and corrective action concerning these deviations (including, where necessary, whether associated batches of product should be recalled from the marketplace), and enable a manufacturer to assure that the corrective action was effective. We believe the regulations in part 111 establish the minimum manufacturing practices necessary to ensure that dietary supplements are manufactured, packaged, labeled, or held in a manner

that will ensure the quality of the dietary supplements during manufacturing, packaging, labeling, or holding operations.

Specifically, the recordkeeping requirements of the regulations in part 111 include establishing written procedures and maintaining records pertaining to: (1) personnel; (2) sanitation; (3) calibration of instruments and controls; (4) calibration, inspection, or checks of automated, mechanical, or electronic equipment; (5) maintaining, cleaning, and sanitizing equipment and utensils and other contact surfaces; (6) water used that may become a component of the dietary supplement; (7) production and process controls; (8) quality control; (9) components, packaging, labels, and product received for packaging and labeling; (10) master manufacturing and batch production; (11) laboratory operations; (12) manufacturing operations; (13) packaging and labeling operations; (14) holding and distributing operations; (15) returned dietary supplements; and (16) product complaints.

Section 111.75(a)(1) (21 CFR 111.75(a)(1)) reflects FDA's determination that manufacturers that test or examine 100 percent of the incoming dietary ingredients for identity can be assured of the identity of the ingredient. However, we recognize that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would result in no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. Section 111.75(a)(1) provides an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency. Section 111.75(a)(1) also sets forth the information a manufacturer is required to submit for an exemption from the requirement of 100 percent identity testing when a manufacturer petitions the Agency for such an exemption to 100 percent identity testing under 21 CFR 10.30 and the Agency grants such exemption.

Description of Respondents: Respondents to this collection of information include manufacturers, packagers and repackagers, labelers and re-labelers, holders, distributors, warehousers, exporters, importers, large businesses, and small businesses engaged in the dietary supplement industry. Respondents are from the private sector (for-profit businesses).

In the **Federal Register** of October 14, 2022 (87 FR 62429), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—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
111.14; records of personnel practices, including documentation of training	15,000	4	60,000	1	60,000
111.23; records of physical plant sanitation practices, including pest control and water quality.	15,000	1	15,000	0.2 (12 minutes)	3,000
111.35; records regarding equipment and utensils, including calibration and sanitation practices.	400	1	400	12.5	5,000
111.95; records of production and process control systems	250	1	250	45	11,250
111.140; records that quality control personnel must make and keep	240	1,163	279,120	1	279,120
111.180; records associated with components, packaging, labels, and product received for packaging and labeling as a dietary supplement.	240	1,163	279,120	1	279,120
111.210; requirements for what the master manufacturing record must include.	240	1	240	2.5	600
111.260; requirements for what the batch production record must include	145	1,408	204,160	1	204,160
111.325; records that quality control personnel must make and keep for laboratory operations.	120	1	120	15	1,800
111.375; records of the written procedures established for manufacturing operations.	260	1	260	2	520
111.430; records of the written procedures for packaging and labeling operations.	50	1	50	12.6	630
111.475; records of product distribution and procedures for holding and distributing operations.	15,000	1	15,000	0.4 (24 minutes)	6,000
111.535; records for returned dietary supplements	110	4	440	13.5	5,940
111.570; records regarding product complaints	240	600	144,000	0.5 (30 minutes)	72,000
Total					929,140

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

TABLE 2—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
111.75; petition for exemption from 100% identity testing	1	1	1	8	8

[1] There are no capital costs 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. We base our estimates for the recordkeeping and reporting burdens on our experience with the recordkeeping and petition activities.

Dated: April 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09411 Filed 5–2–23; 8:45 am]

BILLING CODE 4164–01–P