Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0599]

Submission for Office of Management and Budget Review; Office of Refugee Resettlement Services for Survivors of Torture Program Data Points and Performance Progress Report

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families' (ACF) Office of Refugee Resettlement (ORR) intends to continue collecting demographic, programmatic, and outcome data on Services for Survivors of Torture (SOT) grant recipients and the clients they serve. ORR collects information from the grantee cohort under the Survivors of Torture Program Data Points (PDP) and Program Performance Progress Report (PPR) (Office of Management and Budget (OMB) #0970–0599; Expiration date: February 28, 2026) to learn more about the populations served; the types and effectiveness of services provided; methods, challenges, and facilitators of implementing services; and grant recipients' progress towards programmatic goals. Revisions are proposed as described in the discussion section that follows.

DATES: *Comments due* March 26, 2026.

ADDRESSES: The public may view and comment on this information collection request at: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202602-0970-009.* You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ORR proposes to continue to use the PDP Form and PPR, with revisions, to collect data on the Services for SOT grant recipients and their clients.

The recipients will continue to report their PDP through the ORR Refugee Arrivals Data System (RADS), an information technology platform used for enhanced data collection and record keeping.

Grant recipients will provide aggregated data on new and continuing clients annually, including demographic information, characteristics related to experiences of torture, services received, length of service, and wellbeing across six outcome domains.

Grant recipients will also provide information about community attendance at trainings and pro-bono services donated to the program. In the PPR, grant recipients will provide program narrative and program metric information on grant-funded activities and progress towards grant goals semi-annually.

Information collected will be used in aggregate by ORR to provide reports to stakeholders, including a required Report to Congress, and responses to funding requests.

ORR has made changes to the data collection, which include removing a total of twelve subcategories for two program indicators and reducing the frequency of reporting percentage-based outcomes in the program metrics. ORR has also added one subcategory in one program indicator. Overall, these changes have reduced the estimated reporting burden by 30 percent.

Respondents: Services for SOT grant programs (this may include non-profit social service, health, and higher education organizations, states, municipalities, and for-profit organizations).

Annual Burden Estimates: Estimated annual burden has been updated to reflect a reduction in estimated time per response from an average of 6 hours per response to an average of 4 hours per response.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
PDP Form	35	1	4.2	147
PPRs—Parts A and B	35	2	4.2	294
Total Annual Burden				441

Authority: Section 5(a) of the ''Torture Victims Relief Act of 1998,'' Public Law 105–320 (22 U.S.C. 2152 note) Assistance for Treatment of Torture Victims.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–03617 Filed 2–23–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0686]

Agency Information Collection Activities; Proposed Collection; 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 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 provisions of FDA's regulations regarding current good

manufacturing practice (CGMP) for dietary supplements.

DATES: Either electronic or written comments on the collection of information must be submitted by April 27, 2026.

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 April 27, 2026. 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. [Insert docket number xxxxx] for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.'' 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 electronic and written/paper comments received, 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Christopher Colburn, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8758, *PRABranch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 (DSHEA) (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 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 promulgated 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) 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.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
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 percent 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 its last OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0008]

Advisory Committee; Gastrointestinal Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Gastrointestinal Drugs 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 Gastrointestinal Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the March 3, 2028, expiration date.

DATES: Authority for the Gastrointestinal Drugs Advisory Committee will expire on March 3, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Advisory Committee Oversight and Management Staff, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, (301) 796–9001, *ACOMSSubmissions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 14 CFR 14.40(b) and 41 CFR 102–3.65, and following approval by the Department of Health and Human Services and review by the General Services Administration, FDA is announcing the renewal of the Gastrointestinal Drugs 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 drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug and biologic products for use in the treatment of gastrointestinal and liver diseases. The Committee may consider 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. Meetings are convened as appropriate consistent with the Agency's needs and applicable legal and regulatory authorities.

The Committee shall consist of at least two voting members including the Chair. Subject to legal and regulatory requirements, members and the Chair are selected by and serve at the discretion of the Commissioner or designee. Each member, including the Chair, will be selected from among authorities knowledgeable in the fields of gastroenterology, hepatology, nutrition, surgery, clinical pharmacology, physiology, pathology, and statistics.

Members may be invited to serve for terms of up to four years, or for less time in the discretion of the Commissioner or designee. Non-Federal members of this Committee will serve as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or Ex-Officios.

In addition to the voting members, the Commissioner or designee may identify consumer and/or industry representatives to join the Committee (or serve as alternate representatives) as non-voting representative member(s), via a process consistent with legal and regulatory requirements. Individuals currently employed at FDA-regulated companies, such as pharmaceutical and medical device manufacturers, shall not be selected to serve as members of the Committee unless this Committee is expected to address issues for which inclusion of an industry representative is required by statute. If this Committee includes an industry representative, the Commissioner or designee will determine whether to invite them to participate in meetings on a case-by-case basis, according to applicable legal and regulatory requirements.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees to serve temporarily as voting members and to designate Special Government Employees to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking; or (3) when