comment suggested is likely to lead to one-word answers ''yes'' or ''no,'' which does not provide the type of text response that is needed to conduct text analysis on the data. We did find in cognitive interviews that participants who did not perceive any meaning from a specific drug name said they would be likely to type ''nothing'' into the open-ended text box. Thus, we believe the study in its current form does allow for this possibility.

(Comment 16) One comment suggested very general questions should be asked first and then those that are more specific.

(Response 16) We have ordered the prompts from general to specific in line with the suggested comment.

(Comment 17) One comment proposed that researchers may want to consider reducing the number of drugs queried in the survey from 12 to 6 to elicit the richest text data from respondents and that it may be helpful to give a minimum word count for text responses.

(Response 17) Six drugs will not allow for enough power to make comparisons between the groups. However, if we find that we get many breakoffs (participants who begin the survey but do not complete it) in the pre-test (suggesting the survey burden is too high), we will reconsider the study design.

(Comment 18) One comment recommended that an iterative plan for analysis be developed such that there are checks for both internal and external validity at specified intervals. It further proposed that researchers may want to consider a context-specific analysis plan and argued that one common analysis approach or dictionary may not measure risk, side effects, and other constructs accurately across all drugs.

(Response 18) Though the topic modeling approach is designed to be exploratory for this study, we will calculate coherence metrics to assess model fit as well as perform validation exercises to assess if the generated topics can be easily interpreted.

(Comment 19) One comment recommended that an iterative plan for analysis be created based on a set of preliminary data along with the other research materials, such as the questionnaire, sampling plan, etc., so that it can be reviewed before execution of the full research.

(Response 19) We appreciate the comment. The pre-test will provide the valuable insight to create a specific analysis plan for the main study. The pilot data will help us assess assumptions about how respondents will respond to target names.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
General Consumer Population					
Pretest 1 screener (assumes 80% eligible)	22	1	22	0.08 (5 minutes)	1.8
Pretest 1 survey	17	1	17	0.33 (20 minutes)	5.6
Pretest 2 screener (assumes 80% eligible)	22	1	22	0.08 (5 minutes)	1.8
Pretest 2 survey	17	1	17	0.33 (20 minutes)	5.6
Main study screener (assumes 80% eligible)	413	1	413	0.08 (5 minutes)	33
Main study survey completes	330	1	330	0.33 (20 minutes)	108.9
PCP Population					
Pretest 1 screener (assumes 30% eligible)	57	1	57	0.08 (5 minutes)	4.6
Pretest 1 survey	17	1	17	0.33 (20 minutes)	5.6
Pretest 2 screener (assumes 30% eligible)	57	1	57	0.08 (5 minutes)	4.6
Pretest 2 survey	17	1	17	0.33 (20 minutes)	5.6
Main study screener (assumes 30% eligible)	1,100	1	1,100	0.08 (5 minutes)	88
Main study survey completes	330	1	330	0.33 (20 minutes)	108.9
Total					374

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

As with most online and mail surveys, it is always possible that some participants are in the process of completing the survey when the target number is reached and that those surveys will be completed and received before the survey is closed out. To account for this, we have estimated approximately 10 percent overage for both samples in the study.

Dated: October 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22301 Filed 10–13–22; 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; 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, Agency, or we) 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 December 13, 2022.

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 December 13, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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. FDA–2013–N–1619 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: 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: 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(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).

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 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: October 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22303 Filed 10–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0945–New]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before November 14, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 264–0041. When submitting comments or requesting information, please include the document identifier 0945–New–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Nondiscrimination in Health Programs and Activities.

Type of Collection: New.

OMB No.: 0990–XXXX or 0990–NEW—Office for Civil Rights.

Abstract: This Information Collection Request is for a new collection of information as proposed in the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) Notice of Proposed Rulemaking (NPRM) entitled Nondiscrimination in Health Programs and Activities (RIN: 0945–AA17). The purpose of this information collection is to ensure covered entities (any health program or activity, any part of which is receiving federal financial assistance from the Department and any health program or activity conducted by the Department or Title I entity) adhere to the statutory requirements under Section 1557. The proposed information collection helps covered entities demonstrate compliance with federal civil rights laws and their awareness of their obligations under those laws and respective HHS implementing regulations.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Recipients & State-based Exchanges with 15 or more employees	41,250	1	10	412,500
Recipients & State-based Exchanges	275,002	1	1.75	481,254
Total	316,252			893,754