TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Discontinuation of business—821.1(d)	1	1	1	1	1
Exemption or variance—821.2 and 821.30(e)	1	1	1	1	1
Notification of failure to comply—821.25(d)	2	2	4	1	4
Multiple distributor data—821.30(c)(2)	1	1	1	1	1
Total					7

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Tracking information—821.25(a)	13	1	13	76	988
Record of tracking data—821.25(b)	13	46,260	601,380	1	601,380
Standard operating procedures—821.25(c) [1]	13	1	13	63	819
Manufacturer data audit—821.25(c)(3)	13	1,124	14,612	1	14,612
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	22,000	1	22,000	1	22,000
Total					639,799

[1] One-time burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Acquisition of tracked devices and final distributor data—821.30(a) and (b)	22,000	1	22,000	1	22,000
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	1,100	1	1,100	1	1,100
Total					23,100

Our estimated burden for the information collection reflects an overall increase of 47,526 hours and a corresponding increase of 47,389 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

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–2917]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for Qualitative Data To Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) 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 October 13, 2026.

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 0910–0891. Also include the FDA docket number found in brackets in the heading of this document.

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, *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.

Generic Clearance for Qualitative Data To Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed

OMB Control Number 0910–0891—Extension

OMB's Office of Information and Regulatory Affairs (OIRA) has issued memoranda that provides an overview of administrative flexibilities available to assist agencies in complying with their statutory obligations under the PRA. Among these flexibilities is use of a generic clearance for certain information collection activities. A generic clearance may be appropriate when (1) the need for the data collection can be evaluated in advance, as part of the review of the proposed plan, but (2) the Agency cannot determine the details of the specific individual collections until a later time. Generic clearances cover collections that are voluntary, low-burden, and uncontroversial.

This generic clearance for certain information collection activities supports research conducted by FDA, as authorized under section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)), and is intended to help FDA's Human Foods Program (HFP) understand stakeholders' perceptions, attitudes, motivations, and behaviors. Understanding these perceptions, attitudes, motivations, and behaviors plays an important role in improving FDA's communications which impact various stakeholders and assists in the development of quantitative study proposals to complement other important research efforts in the Agency. To ensure that regulatory actions and communications activities have the highest potential to be received, understood, and accepted by those for whom they are intended, HFP and related FDA offices conduct research and studies relating to the control and prevention of disease as authorized by section 301(a) of the Public Health Service Act (42 U.S.C. 241(a)).

To ensure that communications activities have the greatest effect, we conduct research and studies relating to the control and prevention of disease and the safety and health of the public. FDA is requesting OMB approval for the use of this generic collection of information that allows FDA to use qualitative social/behavioral science data collection techniques (*i.e.,* individual in-depth interviews (IDIs), small group discussions, focus groups, and observations) to better understand stakeholders' perceptions, attitudes, motivations, and behaviors regarding various issues associated with food, dietary supplements, cosmetics, and animal food and feed. Understanding these consumers', manufacturers', and producers' perceptions, attitudes, motivations, and behaviors plays an important role in improving FDA's communications that impact these various stakeholders and in assisting in the development of quantitative study proposals, complementing other important research efforts in the Agency.

To obtain approval for an individual generic submission collection that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (*e.g.,* a copy of the interview or moderator guide, screening questionnaire).

Selection for potential respondents is done via a screening process to match the best possible respondent to each individual generic submission. Respondents to individual requests made under the generic clearance, once approved by OMB, may include a wide range of consumers and other FDA stakeholders, such as producers and manufacturers who are regulated under provisions applicable to FDA-regulated food, dietary supplements, cosmetics, and animal food and feed. Participation is voluntary.

In the **Federal Register** of April 17, 2026 (91 FR 20693), 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 [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual In-Depth Interview Screening	2,400	1	2,400	.08 (5 minutes)	192
Individual In-Depth Interviews	200	1	200	1	200
Focus Group/Small Group Participant Screening	5,400	1	5,400	.08 (5 minutes)	432
Focus Groups/Small Group Discussion	1,800	1	1,800	1.5	2,700
Observation Screening	720	1	720	.08 (5 minutes)	58
Observations	144	1	144	2	288
Total			10,664		3,870

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

These estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. Based on a review of the information collection since our last request for OMB approval, we have adjusted our burden estimate based on actual usage of this collection of information and have decreased the number of responses and hours by half for the first four rows in table 1 with the other rows remaining the same. For the first four rows, we have reduced our estimate for the number of responses from 19,600 to 9,800 responses (a decrease of 9,800 responses) and reduced the number of hours from 7,048 to 3,524 hours (a decrease of 3,524 hours) based on our experience conducting these collections of information. The new burden is estimated at 10,664 responses and 3,870 hours.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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