4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-2917]

Agency Information Collection Activities; Proposed Collection; 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 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 collection of information which allows the submission of individual generic requests for obtaining qualitative data to support social and behavioral research for food, dietary supplements, cosmetics, and animal food and feed.

DATES: Either electronic or written comments on the collection of information must be submitted by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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 **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. 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. FDA-2026-N-2917 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Qualitative Data to Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed." 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, 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.

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) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. section 393(d)(2)(D)), 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 of the Public Health Service Act (42 U.S.C 241(a)).

To ensure that communications activities have the highest 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 FDA-regulated food, dietary supplements, cosmetics, and animal food and feed. Participation is voluntary.

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

Table 1. --Estimated Annual Reporting Burden[1]

Activity	Number of Respondents	No. 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 these items, as listed in the first four rows in table 1. 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 total reduction in burden, therefore, is estimated as 9,800 responses and 3,524 hours. 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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