



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-5841]

**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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the creation of a new collection of information entitled "Generic Clearance for Qualitative Data to Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed."

DATES: Submit either electronic or written comments on the collection of information 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. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL*

REGISTER]. 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 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-2019-N-5841 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.

- 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 docket, 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.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@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 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-New

This notice announces the FDA information collection request from the OMB for a generic clearance that will allow 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 and cosmetic products, dietary supplements, and animal food and feed. Understanding consumers', manufacturers', and producers' perceptions, attitudes, motivations, and behaviors plays an important role in improving FDA's communications impacting these various stakeholders and in assisting in the development of quantitative study proposals, complementing other important research efforts in the Agency.

FDA will only submit a collection for approval under this generic clearance if it meets the following conditions:

- the collections are voluntary;
- the collections are low burden for participants (based on considerations of total burden hours, total number of participants, or burden hours per participant) and are low cost for both the participants and the Federal Government;
- the collections are noncontroversial;
- personally identifiable information (PII) is collected only to the extent necessary¹ and is not retained;
- information gathered will not be used for the purpose of substantially informing influential policy decisions;² and
- information gathered will yield qualitative information; the collections will not be designed or expected to yield statistical data or used as though the results are generalizable to the population of study.

If these conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process.

To obtain approval for a 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).

FDA will submit individual qualitative collections under this generic clearance to the OMB. Individual qualitative collections will also undergo review by FDA's Institutional Review Board, senior leadership in the Center for Food Safety and Applied Nutrition, and PRA specialists.

¹ For example, collections that collect PII to provide remuneration for participants of focus groups and cognitive laboratory studies will be submitted under this request. All Privacy Act requirements will be met.

² As defined in OMB and Agency Information Quality Guidelines, "influential" means that "an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions."

Description of Participants: Participants in this collection of information may include a wide range of consumers and other FDA stakeholders such as producers and manufacturers who are regulated under FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed.

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

Table 1.--Estimated Annual Reporting Burden, by Anticipated Data Collection Methods

Type of Interview	Number of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
Individual In-Depth Interview Screening	4,800	1	4,800	.08 (5 minutes)	384
Individual In-Depth Interviews	400	1	400	1	400
Focus Group/Small Group Participant Screening	7,200	1	7,200	.08 (5 minutes)	576
Focus Group/Small Group Discussion	2,400	1	2,400	1.5	3,600
Observation Screening	720	1	720	.08 (5 minutes)	58
Observations	144	1	144	2	288
Total	15,664				5,306

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

The total estimated annual burden is 5,306 hours and 15,664 responses. Current 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. The number of participants to be included in each new collection will vary, depending on the nature of the compliance efforts and the target audience.

Dated: January 31, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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