are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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Dated: June 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14375 Filed 7–2–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5841]

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) 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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by August 5, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted *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 title of this information collection is ''Generic Clearance for Qualitative Data to Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed.'' Also include the FDA docket number found in brackets in the heading of this document.

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, *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–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, small group discussions, focus groups, and observations) to understand stakeholders' perceptions, attitudes, motivations, and behaviors better 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 necessary [1] 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.

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.

In the **Federal Register** of February 10, 2020 (85 FR 7564), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although five comments

[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.''

were received, they were not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

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	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual In-Depth Interview Screening.	4,800	1	4,800	0.08 (5 minutes)	384
Individual In-Depth Interviews	400	1	400	1	400
Focus Group/Small Group Participant Screening.	10,800	1	10,800	0.08 (5 minutes)	864
Focus Group/Small Group Discussion.	3,600	1	3,600	1.5	5,400
Observation Screening	720	1	720	0.08 (5 minutes)	58
Observations	144	1	144	2	288
Total	20,464				7,394

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

The total estimated annual burden is 7,394 hours and 20,464 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.

The estimated burden hours for focus groups for this collection of information have been increased from the burden published in the **Federal Register** on February 10, 2020, to the burden published in this **Federal Register** notice. The adjustment in burden hours for focus groups reflects the increased need for this type of data collection across the above-mentioned topic areas.

Dated: June 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14365 Filed 7–2–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1261]

Agency Information Collection Activities; Proposed Collection; Comment Request; Study of Disclosures to Health Care Providers Regarding Data that Do Not Support Unapproved Use of an Approved Prescription Drug

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 research entitled ''Study of Disclosures to Health Care Providers Regarding Data that Do Not Support Unapproved Use of an Approved Prescription Drug.''

DATES: Submit either electronic or written comments on the collection of information by September 4, 2020.

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 September 4, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 4, 2020. 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–2020–N–1261 for ''Study of Disclosures to Health Care Providers Regarding Data that Do Not Support Unapproved Use of an Approved Prescription Drug.'' 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