address questions or concerns that may arise. Pilot program participants will also be asked to provide written and verbal feedback during their training and after they submit the simulated registration and listing information. This feedback will assist OCAC and OCS in ensuring the electronic submission portal is usable and functional to ensure industry will be able to meet its statutory obligations. OCAC and OCS estimate that each individual participant's involvement may require about 8 hours over the 2-week period. OCAC and OCS are soliciting applications from members of the cosmetic product industry who will be required to register their facilities and list their products, such as cosmetic product manufacturers, as well as entities that may act as authorized agents for manufacturers. At its discretion, OCAC and OCS may withdraw a participant from the pilot program for not completing the requested activities within requested timeframes.

None of the information submitted during the pilot will fulfill a participant's registration and listing responsibilities pursuant to MoCRA. Participants will need to submit their information in the electronic registration and listing system once it is available for submissions or through a paper form to fulfill their registration and listing responsibilities pursuant to MoCRA.

Entities that may be eligible to participate in this voluntary pilot program for cosmetic product facility registration and listing are limited to those firms following the procedures set out in section III. and that also meet the two selection criteria that follow:

1. required to submit cosmetic product facility registration and listing information to FDA pursuant to MoCRA by December 29, 2023; and,

2. willing to provide feedback on the cosmetic product facility registration and listing electronic submission process.

III. Applications for Participation

To be considered to participate in the pilot program, entities should submit a statement of interest for participation to *eRLC.testing@fda.hhs.gov.* The statement of interest should include the following information: company and contact name, contact phone number, and contact email address, size of the company (*i.e.,* number of personnel and the approximate amount of revenue per year), agreement to the selection criteria in section II of this document, as well as the number of cosmetic product(s) and a description of the cosmetic product(s) intended to be submitted in the pilot program in enough detail to verify that the cosmetic product(s) are not drug product(s). A firm can choose to submit information for a subset of their products rather than all their products in the pilot program.

Additionally, although not required for consideration, FDA is interested in whether you are a manufacturer or may act as an authorized agent, and whether you have previously submitted registration and listing information to the Agency for any regulated product. Once statements of interest for participation in the pilot are received, FDA will contact interested applicants to confirm selection for the pilot program. FDA will not notify interested applicants who are not selected for the pilot program. FDA will select no more than nine participants, who best meet the selection criteria and who reflect a broad spectrum of cosmetic product manufacturers and processors, including companies that range in size and develop a range of products, or are an authorized agent. In the event a large number of submissions are received, FDA may only review a small number of submissions in order to identify nine (or fewer) for the pilot program.

Dated: August 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16772 Filed 8–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1157]

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, the Agency, or we) 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 September 7, 2023.

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: 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: 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 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 supports research intended to help the Center for Food Safety and Applied Nutrition understand stakeholders' perceptions, attitudes, motivations, and behaviors. To ensure that communications activities have the highest effect, we will 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 indepth interviews, 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 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 assists 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 and cosmetic products, dietary supplements, and animal food and feed. Participation is voluntary.

In the **Federal Register** of April 10, 2023 (88 FR 21193), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but was not responsive to the four collection of information topics solicited and therefore will not be discussed.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of interview	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual Indepth Interview Screening	4,800	1	4,800	0.08 (5 minutes)	384
Individual Indepth Interviews	400	1	400	1	400
Focus Group/Small Group Participant Screening	10,800	1	10,800	0.08 (5 minutes)	864
Focus Groups/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.

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 collections we have conducted under this generic collection of information have informed and helped us better understand stakeholder perceptions, attitudes, motivations, and behaviors to help us improve our communications to them.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16924 Filed 8–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–2439]

QTc Information in Human Prescription Drug and Biological Product Labeling; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''QTc Information in Human Prescription Drug and Biological Product Labeling.'' This guidance is intended to assist applicants with incorporating corrected QT (QTc) interval prolongation-related information into the labeling of non-antiarrhythmic human prescription drug and biological products. The guidance provides recommendations on how and where to appropriately include the clinically relevant information on QTc interval prolongation in the labeling, in accordance with regulatory requirements for the content and format of human prescription drug labeling.

DATES: Submit either electronic or written comments on the draft guidance by October 10, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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