per response) to yield an approximate 2.3 to one ratio of eligible participants. We will need to screen approximately 112,000 potential parents and young adults each month (resulting in 2,688,000 screeners) over the study period. Since the eligible age for data collection is 12 to 20 years old, we intend to screen parents of eligible youth, as well as young adults. Parents of the youth participants determined to be eligible through the screener will provide parent permission (3 minutes per response). We estimate that 2,016,000 of the parents who complete the screener will provide their permission for their youth to complete the online survey (approximately 75 percent of the 2,688,000 screened). Eligible youth (2,016,000) will provide their assent (3 minutes per response) to participate in the online survey (25 minutes per response). Participants that are 18 to 20 (19 to 20 in Alabama and Nebraska in accordance with state law) will complete the screener for themselves and provide their consent (3 minutes per response) to participate in the online survey. We estimate that approximately 25 percent of the 48,000 completed surveys will come from young adults aged 18 to 20 (19 to 20 in Alabama and Nebraska).

Over the course of the study period, we intend to survey approximately 2,000 youth and young adults ages 12 to 20 per month for 24 months. From these completed screeners, we estimate that we will obtain data from 36,000 youth and 12,000 young adults. This will give us a total of 48,000 participants for the study. The survey will be repeated with a new cross-sectional sample approximately every month over a period of 24 months; however, some participants will complete more than one wave. These 48,000 respondents will receive an invitation email with a link to take the survey (4 minutes), six reminder emails (3 minutes each), and a thank you email (3 minutes) upon completion of the study for a total of 25 minutes for respondents to read and respond to the emails.

Dated: April 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08945 Filed 4–26–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1466]

Good Manufacturing Practices for Cosmetic Products Listening Session; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a virtual listening session entitled ''Good Manufacturing Practices for Cosmetic Products Listening Session.'' The purpose of the listening session is to consult cosmetics manufacturers, including smaller businesses, consumer organizations, and other experts, to inform Agency efforts to develop regulations to establish good manufacturing practices for facilities that manufacture or process cosmetic products distributed in the United States.

DATES: The virtual listening session will be held on June 1, 2023, from 10 a.m. to 1 p.m. Eastern Daylight Time (EDT) or until after the last public commenter has spoken, whichever occurs first. Submit requests to make oral presentations at the listening session by 6 p.m. EDT, May 18, 2023. Either electronic or written comments on this listening session must be submitted to the docket by July 3, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Additional details, such as registration information, are available at *https://www.fda.gov/cosmetics/cosmetics-news-events/public-meeting-good-manufacturing-practices-cosmetic-products-06012023.*

FDA is establishing a public docket for this listening session. 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. EDT at the end of July 3, 2023. 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–2023–N–1466 for ''Good Manufacturing Practices for Cosmetic Products Listening Session.'' 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: Deborah Smegal, Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., Rm. 1037 (HFS–125), College Park, MD 20740, 240–402–1130, (this is not a toll-free number), email: *MoCRAGMPMeeting@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117–328) into law, which included the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). Among other provisions, MoCRA added section 606 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), requiring FDA to establish by regulation good manufacturing practices (GMPs) for facilities that manufacture or process cosmetic products distributed in the United States. MoCRA specifies that these GMPs are to be consistent, to the extent practicable, and appropriate, with national and international standards, in accordance with section 601 of the FD&C Act (21 U.S.C. 361). Any such regulations shall be intended to protect the public health and ensure that cosmetic products are not adulterated. As required by MoCRA, before issuing rulemaking, FDA must consult with cosmetics manufacturers, including smaller businesses, consumer organizations, and other experts selected by FDA. Further, FDA must take into account the size and scope of the businesses engaged in the manufacture of cosmetics, and the risks to public health posed by such cosmetics and provide sufficient flexibility to be practicable for all sizes and types of facilities to which such regulations will apply. Such regulations must include simplified good manufacturing practice requirements for smaller businesses, as appropriate, to ensure that such regulations do not impose undue economic hardship for smaller businesses and may include longer compliance times for smaller businesses. In addition, MoCRA added section 612 of the FD&C Act, which exempts certain small businesses from the GMP requirements.

FDA issued a draft guidance, entitled ''Draft Guidance for Industry: Cosmetic Good Manufacturing Practices,'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-cosmetic-good-manufacturing-practices*) in 2013. We intend to withdraw or revise and reissue this draft guidance, as appropriate, based on the GMP rulemaking.

II. Topics for Comment

To facilitate input on good manufacturing practices for cosmetic products, FDA has developed a series of topics covering the types of information that we are interested in obtaining. In all cases, FDA encourages stakeholders to provide the specific rationale and basis for their comments, including any available supporting data and information.

Respondents need not reply to all topics listed. Please identify your answers as responses to a specific topic.

Topics Related to Good Manufacturing Practices

1. Identify any national or international standard (*e.g.,* International Organization for Standardization (ISO) standard 22716:2007) and the extent to which it would be practicable for good manufacturing practice regulations for cosmetic products to be consistent with such standard. Please include whether there are specific items in the standard which are perceived to be burdensome or for which a less burdensome alternative exists that would protect the public health and ensure that cosmetic products are not adulterated.

2. Describe what constitutes sufficient flexibility within good manufacturing practices for cosmetic products to ensure regulations are practicable for all sizes and types of facilities to which such practices may apply. Please take into account the size and scope of the businesses engaged in the manufacture of cosmetic products and the risks to public health posed by cosmetic products.

3. Describe what constitutes simplified good manufacturing practices requirements for cosmetic products for smaller businesses to ensure regulations do not impose undue economic hardship.

4. Describe appropriate compliance times for good manufacturing practices regulations.

Topics Related to Economic Impact

5. To what extent are manufacturers of cosmetic products already following a national or international standard for good manufacturing practices? For manufacturers of cosmetic products that are not currently following such a national or international standard, what would it cost to implement good manufacturing practices consistent with such a standard?

6. Please provide reports or examples of adverse events or recalls associated with a cosmetic product that were linked to manufacturing practices. How would implementing good manufacturing practices impact the likelihood of recall of cosmetics products? How would implementing good manufacturing practices impact the likelihood of consumers experiencing adverse events from the use of cosmetics products? How would these impacts differ by type of cosmetic product?

III. Participating in the Listening Session

Registration: To register for the free virtual listening session, please visit the following website: *https://www.fda.gov/cosmetics/cosmetics-news-events/public-meeting-good-manufacturing-practices-cosmetic-products-06012023.* Registration may be performed at any time before or during the listening session.

Information on requests for special accommodations due to a disability will be provided during registration.

Requests to Provide Oral Presentations: During online registration you may indicate if you wish to present during the listening session. Requests to provide public comments during the listening session should be submitted by 6 p.m. EDT, May 18, 2023. We will do our best to accommodate requests to

make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Based on the number of requests we receive, we will determine the amount of time allotted to each presenter (which we expect to be approximately 3 minutes) and the approximate time each oral presentation is to begin. We will select and notify participants at the time of registration, or by May 19, 2023. If selected for presentation, participants must email presentation materials to *MoCRAGMPMeeting@fda.hhs.gov* no later than May 22, 2023, 11:59 p.m. EDT. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Listening Session: This listening session will be webcast. Please register online (as described above). Registrants will receive a hyperlink that provides access to the webcast.

FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register,** but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the listening session is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: April 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08942 Filed 4–26–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0390]

Agency Father Generic Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, Health and Human Service, HHS.

ACTION: Notice and request for comments. Office of the Assistant Secretary for Public Affairs is requesting OMB approval for a new father generic clearance.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before May 29, 2023.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 264–0041. When requesting information, please include the document identifier 0990–0390–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Challenge and Prize Competition Solicitations.

Type of Collection: Extension OMB No. 0990–0390—Office of the Assistant Secretary for Health (OASH).

Abstract: The Office of the Secretary (OS), Department of Health & Human Services (HHS) requests that the Office of Management and Budget (OMB) approve a request for an extension of generic clearance approval of the information collected for challenge and prize competition solicitations. Burden hours were increased from 333 to 558.3 total burden hours to provide more time for respondents to complete forms that may include more questions.

Challenges and prize competitions enable HHS to tap into the expertise and creativity of the public in new ways as well as extend awareness of HHS programs and priorities. Within HHS, the Office of the Assistant Secretary for Health (OASH) has taken lead responsibility in coordinating challenges and prize competitions and implementing policies regarding the use of these tools. HHS's goal is to engage a broader number of stakeholders who are inspired to work on some of our most pressing health issues, thus supporting a new ecosystem of scientists, developers, and entrepreneurs who can continue to innovate for public health.

The generic clearance is necessary for HHS to launch several challenges or prize competitions annually in a short turnaround. The information collected for these challenges and prize competitions will generally include the submitter's or other contact person's first and last name, organizational affiliation and role in the organization (for identification purposes); email address or other contact information (to follow up if the submitted solution is selected as a finalist or winner); street address (to confirm that the submitter or affiliated organization is located in the United States, for eligibility purposes); information confirming whether the submitter's age is 13 years or older (to ensure compliance with the Children's Online Privacy Protection Act of 1998, 15 U.S.C. 6501–6505 (COPPA)) or 18 years or older (to ensure necessary consents are obtained); and a narrative description of the solution. HHS may also request information indicating the submitter's technical background, educational level, ethnicity, age range, gender, and race (to evaluate entrants' diversity and backgrounds), how the submitter learned about the challenge or prize competition and what the submitter currently understands about the HHS agency hosting the challenge or prize competition (to gauge the effect of the challenge or prize competition on increasing public awareness of HHS programs and priorities, and generally to enable HHS to improve its outreach strategies to ensure a diverse and broad innovator constituency is fostered through the use of challenges and prize competitions). Finally, HHS may ask for additional information tailored to the challenge or prize competition through structured questions. This information will enable HHS to create and administer challenges and prize competitions more effectively.

Upon entry or during the judging process, solvers under the age of 18 will be asked to confirm parental consent, which will require them to obtain and provide a parent or guardian signature in a format outlined in the specific criteria of each challenge or prize competition in order to qualify for the contest. To protect online privacy of minors, birthdate may be required by the website host to ensure the challenge platform meets the requirements of COPPA. Eligibility to win a cash prize will be outlined in the specific criteria of each contest and will only apply to U.S. citizens, permanent residents, or private entities incorporated in and maintaining a primary place of business in the U.S. To administer the cash prize, HHS will need to collect additional relevant payment information—such as Social Security Number and/or Taxpayer ID and information regarding the winners' financial institutions—in