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[FR Doc. 2018–14172 Filed 6–29–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2027]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey of Current Manufacturing Practices for the Cosmetics Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 a new information collection: A survey of the cosmetics industry on their current manufacturing practices.

DATES: Submit either electronic or written comments on the collection of information by August 31, 2018.

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 August 31, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of August 31, 2018. 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–2018–N–2027 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Survey of Current Manufacturing Practices for the Cosmetics Industry.'' 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 dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/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, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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.

Survey of Current Manufacturing Practices for the Cosmetics Industry—OMB Control Number 0910—New

FDA has the responsibility to protect public health and, as part of this broad mandate, oversees the safety of the nation's cosmetic products. The Federal Food, Drug, and Cosmetic Act (FD&C Act) prohibits the introduction into interstate commerce of any cosmetic that is adulterated or misbranded.

The FD&C Act defines cosmetics as articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, deodorants, and tattoo inks, as well as any substance intended for use as a component of a cosmetic product. Some cosmetic products are also regulated as drugs.

As with other commodities FDA regulates, the safety of cosmetic products can be ensured in part through a manufacturer's approach to the management of cosmetic quality. To date, FDA has not identified in the published literature any systematic, detailed study of the diversity of the practices and standards employed across the cosmetic industry to ensure product quality and safety. This study is intended to fill this gap. FDA proposes to conduct a voluntary survey of cosmetics establishments to identify the current quality management and safety practices in the cosmetic industry.

The survey instrument will collect data, on a voluntary basis, from cosmetic product manufacturers on the following topics:

- Written Procedures and Documentation—including written procedures and records for manufacturing involving personnel, raw materials, processing, cleaning, maintenance, finished products, and training.
- Buildings and Equipment—including facility space, pest control, practices ensuring the cleanliness and sanitation, water usage and treatment, and the proper functioning and operation of equipment.
- Materials and Manufacturing—including practices for inventory management, labeling and storage of raw materials, closures, and in process materials; and in process standard operating procedures.
- Quality Control/Product Testing—including the scope of the quality control unit, laboratory testing, dealing with rejected or returned products and complaints, and corrective actions.

In addition, FDA will obtain the characteristics of surveyed establishments such as the types of cosmetics produced, published standards and guidelines followed, the number of employees, the volume of production, and the approximate revenue. The survey will be administered by web or by mail (respondent choice) and it will be directed to the Plant Manager of the cosmetics establishment.

This is a new, one-time data collection. FDA does not plan to collect this data from the cosmetics industry on an ongoing basis.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Survey Invitation	898	1	898	0.08 (5 minutes)	71.84
Survey	564	1	564	0.5 (30 minutes)	282.00
Total					353.84

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

We will select a sample of 898 establishments. After adjusting for ineligibility (*i.e.,* firms that do not produce cosmetic products and those no longer in operation) and a response rate of 70 percent, we expect 564 completed surveys.

We expect each individual survey invitation to take 5 minutes (0.08 hour) to complete. Multiplying by the 898 establishments that will receive the survey invitation, we estimate the time burden of the survey invitation to be 71.84 hours. We expect each individual survey to take 30 minutes (0.5 hour) to complete. Multiplying by the estimated 564 establishments that will complete the survey, we estimate the time burden of the survey to be 282 hours. We estimate the total hourly reporting burden for this collection of information to be 353.84 hours.

Dated: June 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14158 Filed 6–29–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Lists of Designated Primary Medical Care, Mental Health, and Dental Health Professional Shortage Areas

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice informs the public of the availability of the complete lists of all geographic areas, population groups, and facilities designated as primary medical care, mental health, and dental health professional shortage