

4. In a situation where the output of prescription drug-use-related software includes a benefit claim about the drug, what should FDA consider when providing recommendations on how to appropriately address the balancing of benefit information and risk information?

5. Does the proposed framework appropriately characterize the types of prescription drug-use-related software output that should be submitted for advisory comment? (See Section II.C., Prescription Drug-Use-Related Software Output That Constitutes Promotional Labeling) Are there other examples for which advisory comment should be recommended because there is a strong potential that the prescription drug-use-related software output will increase the potential for harm to health if used with a drug?

6. Does the proposed framework appropriately identify the materials and information that should be submitted by drug sponsors as part of a voluntary request for comment under § 202.1(j)(4)? Are there other materials or information FDA should consider in its evaluation of whether prescription drug-use-related software output submitted by drug sponsors is consistent with FDA-required labeling and is truthful and not misleading (e.g., human factors study results)?

7. Regarding software functions, FDA's proposed expectation is that sponsors are responsible for ensuring that prescription drug-use-related software reliably produces its output as intended. Is this approach sufficient to ensure patient safety?

8. FDA recognizes that software will have frequent updates, many of which will not alter prescription drug-use-related software functionality. FDA proposes that for prescription drug-use-software output that is considered promotional, if changes in the software do not alter the output experienced by the user, FDA would not need to be notified of those changes. Does this approach strike an appropriate balance between allowing for software innovation while providing adequate oversight of sponsor communications about their prescription drugs?

9. What can be done to ensure that the end user has access to the prescription drug-use-related software that is appropriate to the specific drug dispensed at the pharmacy (e.g., in cases of generic substitution)?

10. What issues should the Agency consider as it develops this proposed framework in order to facilitate timely generic competition for prescription drugs that are approved with prescription drug-use-related software output included in the FDA-required labeling?

Dated: November 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2027]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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: Fax written comments on the collection of information by December 20, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910—New and title “Survey of Current Manufacturing Practices for the Cosmetics Industry.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, 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.

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;

cosmetics are also to be safe and properly labeled.

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. This study is intended to fill this gap. FDA proposes to conduct a voluntary survey of cosmetics establishments to identify the current manufacturing 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.

In the **Federal Register** of July 2, 2018 (83 FR 30940), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received three comments. FDA thanks the commenters for their comments and provides our responses below.

The first comment expressed concern that the collection was voluntary, and a number of manufacturers may not participate, which will not inform FDA of manufacturers who are not observing good manufacturing practices. They also indicated that they feel the survey could help set future standards for the industry. In response to this comment, FDA notes that this survey is being conducted to inform FDA with updated information about the practices and

standards employed across the cosmetics industry. With regard to identifying manufacturers who are not observing good manufacturing practices, the survey is structured to provide FDA with anonymized, updated cosmetic industry information, not individual response information about any of its participants.

The second comment addressed specific PRA issues of necessity, burden estimate, quality and utility of the survey, and method of collection. The commenter feels that the survey is not necessary for proper FDA oversight of the industry because this information is already available to FDA through its facility inspections. They also indicated that they had not seen the actual questions on the survey, and therefore felt the burden estimate was not feasible. They suggested that FDA partner with outside sources to assist FDA in gathering information about the industry and thought that web or mail collection was reasonable.

In response to the second comment, FDA noted in the **Federal Register** of July 2, 2018 that 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.” FDA is conducting this survey to fill this gap in knowledge, and this survey is necessary to achieve this goal. With regard to the survey itself, it is (and has been) available at the FDA Docket assigned to this collection (FDA–2018–N–2027). We agree that the burden is likely greater than 30 minutes, and based on results of our pretest with six individuals, we have increased the burden estimate to 60 minutes. FDA’s contractor did consult with industry stakeholders in the development of the survey instrument. Finally, FDA thanks the commenter for their comments and thoughts that our suggested method of web or collection method was reasonable.

The third comment was not related to the PRA and will not be addressed at this time.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

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	1	564
Total	635.84

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. Previously, we estimated that the survey would take 30 minutes to complete. However, based on our pretest with six individuals, we now expect each individual survey to take, on average, 60 minutes (1 hour) to complete. Multiplying by the estimated 564 establishments that will complete the survey, we estimate the time burden of the survey to be 564 hours. We estimate the total hourly reporting burden for this collection of information to be 635.84 hours.

Dated: November 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2012–N–0129]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions; Section 351(k) Biosimilar Applications

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.

DATES: Fax written comments on the collection of information by December 20, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0719. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St.,