

United States Food and Drug Administration

Survey of Current Manufacturing Practices for the Cosmetics Industry

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

Terms of Clearance: None. This is a new collection of information.

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (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 (FD&C) Act, Section 301 (21 U.S.C. 331), prohibits the introduction into interstate commerce of any cosmetic that is adulterated or misbranded; federal law also requires that "cosmetics are safe and properly labeled" (21 U.S.C. 393(b)(2)(D)).

Under the FD&C Act, cosmetics are defined 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" (FD&C Act, sec. 201(i)). 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 that could enlighten FDA on the diversity of practices and standards employed across the cosmetic industry. FDA's knowledge about the industry is limited to what is submitted to the Agency by industry through their narrow participation in the Voluntary Cosmetic Registration Program. FDA has scant information from inspections of cosmetics manufacturing facilities. This data collection is aimed at filling that knowledge gap.

Over the past several years, FDA has had an increasing number concerns from microbial contamination and the presence of chemical contaminants in cosmetic products, resulting in recalls in some cases and Congressional inquiries in others. Additionally, there have been a number of safety issues raised by consumers, Congress, and industry. The proposed research will be conducted with the aim of identifying the current baseline

manufacturing practices in the cosmetic industry and identifying if any of these concerns would be addressed with improved manufacturing practices. The research will also attempt to quantify the incremental costs to firms of the improved manufacturing practices to be considered at the baseline.

Finally, if Congress is to pass new Cosmetic legislation, FDA will need to have better knowledge of the industry (who the entities are, the size of the firms, and the current practices) to better understand how to implement the legislative changes. FDA would use the information from the survey in the aggregate to help improve the Agency's safety oversight.

2. Purpose and Use of the Information Collection

This study is intended to provide information regarding current baseline manufacturing practices in the cosmetics industry which support product quality and safety and to derive the associated implementation costs of these practices. The survey instrument will collect data from cosmetic manufacturers on the following topics:

- Written Procedures and Documentation – including written procedures and records for manufacturing on 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 for 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, corrective action.

In addition, we 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 help FDA identify the extent to which cosmetics manufacturers in the US are currently following the Good Manufacturing Practices (GMPs) set out by other organizations (ISO, trade groups, foreign governments, etc.). In the US, each man uses, on average, 6 cosmetic products per day and each woman uses an average of 12 cosmetic products per day. This survey would help FDA understand current baseline practices and would inform decision-making around whether our own GMPs are needed to help protect the public health, given recent concerns over the safety of cosmetic products, and what the cost to industry would be to implement those GMPs.

If we find that manufacturers in the US are already largely following the GMPs set out by other organizations, then that might suggest that requiring GMPs might not help to solve the public health concerns currently surrounding cosmetic products. On the other hand, if GMPs are largely not being followed, this survey could help us identify areas where improvements in the manufacturing process could lead to the increased safety of cosmetics products.

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

The respondents to this collection of information are all U.S. cosmetics manufacturing establishments.

The survey instrument is included as Appendix 1.

3. Use of Improved Information Technology and Burden Reduction

We will collect the information online from participants using a Web-based questionnaire. The technology is non-intrusive, allows participants to interact with the questionnaire freely, and minimizes participant burden. Participants will be offered a paper version of the questionnaire if they prefer. Based on our experience, we estimate that at least 65% of the respondents will choose the electronic version. Note that this estimate of 65% is not our estimate of the overall expected response rate to the survey as discussed in section 12 of this document and in further detail in Part B.

The web version of the survey instrument is included as Appendix 2.

4. Efforts to Identify Duplication and Use of Similar Information

The proposed research is not duplicative of existing information.

5. Impact on Small Businesses or Other Small Entities

The cosmetics industry includes small businesses; thus, there is the need to collect data from small businesses to provide an accurate description of the cosmetics industry. We expect about 463, or 85%, of the survey respondents to be a small business as defined by the Small Business Administration (SBA). FDA has developed a highly focused survey instrument and is utilizing the Internet and the U.S. Postal Service as its modes of data collection based on the preferences of the individual small entities.

The survey instrument contains built-in skip logic, prompts, and edits that will minimize the time required to answer the questions. The mail instrument will be specially designed to be easily read with a logic pattern that will also minimize the time for completion. Thus, the reporting burden by small entities will be modest. No further reductions in respondent burden are possible without rendering the survey ineffective.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of July 2, 2018 (83 FR 30940). FDA received 3 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 following code. 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 following code, 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 Paperwork Reduction Act 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 the 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 its Federal Register notice of July 2, 2018 (83 FR 30940) 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-22018-N-2027). We agree that the burden is likely greater than 30 minutes, and based on results of our pretest with 6 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 their thoughts that our suggested method of web or collection method was reasonable.

The third comment was not related to the Paperwork Reduction Act, and will not be addressed at this time.

9. Explanation of Any Payment or Gift to Respondents

No payment, gifts, or other remuneration will be offered to respondents.

10. Assurance of Confidentiality Provided to Respondents

RTI International, an independent contractor, will be responsible for collecting the information. The privacy of the survey data will be ensured by enacting procedures to prevent unauthorized access to respondent data and by preventing the public disclosure of the responses of individual respondents. In addition, the questionnaire will contain a statement indicating that responses will be kept secure to the extent provided by law. At the conclusion of data collection, the contractor will provide the agency with a database of the survey responses. However, the database will not include any identifying information, such as plant name, respondent name, or plant address. In addition, the contractor will conduct data masking techniques such as dropping or collapsing categories for identifying variables. Only the deidentified survey data will be delivered to FDA. Any survey results reported by FDA, based on the deidentified data it receives, would be in aggregated statistical form.

The privacy of the information submitted is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). The proposed data collection has received an exempt status from our contractor's Institutional Review Board (IRB) as well as FDA's Research Involving Human Subjects Committee (RIHSC).

All electronic data will be maintained in a manner consistent with the Department of Health and Human Services' Automatic Data Processing (ADP) Systems Security Policy as described in the DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products), 79 Fed. Reg. 36536 (June 27, 2014).

Privacy Act Review

In developing this proposed collection, staff from FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Office of the Commissioner's Economics Staff consulted the FDA Privacy Officer to identify potential risks to the privacy of individuals whose information may be handled by or on behalf of FDA.

FDA has determined that this collection includes the submission of limited, non-sensitive, work-context personally identifiable information (PII) to contractors working on behalf of the FDA. FDA has also determined that this collection is not subject to the Privacy Act of 1974 and the Act's requirements, including to provide specific notice

statements on forms used to collect PII, do not apply. Nevertheless, FDA and contractor RTI International (“RTI,” “our contractor,” or “the contractor”) will provide notice to respondents regarding data collection and use, and will apply administrative, physical and technical controls to safeguard the data.

RTI, as an independent contractor performing services on behalf of the FDA, will be responsible for collecting survey response information from individual respondents (company points of contact) on behalf of the FDA. FDA has provided RTI with necessary company/major manufacturer contact information consisting of company name, company street address and a general company phone number for RTI to use in administering the survey. RTI uses this information to contact companies to ask that they participate in the survey and provide contact information for a knowledgeable company employee (point of contact, e.g., plant manager) who might provide responses to a survey questionnaire. The personally identifiable contact information for these individuals that is gathered by RTI is all professional/work contact information consisting of the individual’s name, work title, work phone, and work email and mailing addresses. RTI collects completed questionnaires and provides the response information to FDA devoid of all business contact PII as well any information that would identify the company associated with a response.

RTI will limit the post-collection transmission and proliferation of collected business contact information PII and will not transmit collected business contact information to FDA. Rather, RTI will remove PII business contact information from survey responses and any other data it provides to FDA. At the conclusion of data collection, the contractor will provide the agency with a database of the survey responses, and that database will not include any potential company or individually identifying information, such as plant name, respondent name, or plant address. In addition, the contractor will conduct data masking techniques such as dropping or collapsing categories holding identifying variables to minimize risk of identification and to ensure that only the deidentified survey data is delivered to FDA. Likewise, analysis of the survey results will be reported only in aggregated, statistical, non-identifiable form.

RTI stores survey responses and associated PII in a secure repository and in accordance with applicable record keeping requirements; RTI does not further use, process or share this information after initial collection. RTI will safeguard the privacy of respondents and the confidentiality of the survey data by employing procedures to restrict access to respondent data, limiting it to individuals within RTI who have a need to access the data to perform authorized duties under the contract with the agency. RTI policies also prohibit the public disclosure of the responses of individual respondents. RTI provides individuals assurances of privacy and confidentiality within the questionnaire which will contain a statement indicating that RTI will keep responses confidential and not disclose them unless required by law.

11. Justification for Sensitive Questions

The study does not include any questions that are of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Invitation	898	1	898	0.08 (5 minutes)	71.84
Survey	564	1	564	1	564.00
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 the survey invitation to take 5 minutes (0.08 hours) 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, as noted in the 60 day notice for public comment in the FEDERAL REGISTER of July 2, 2018 (83 FR 30940), we estimated that the survey would take 30 minutes to complete. However, based on our pretest with six individuals, we now expect the survey to take 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. Summing these, we estimate the total time burden to be 635.84 hours.

12b. Annualized Cost Burden Estimate

The total cost to all respondents for this collection of information is estimated to be \$64,109.72. We estimate the average hourly wage for respondents is reflected by the mean hourly wage of \$18.88¹ (the May 2016 median hourly wage rate for U.S secretaries and administrative assistants (Occupation Code 43-6010) in the Soap, Cleaning Compound, and Toilet Preparation Manufacturing industry (NAICS code 325600.) Doubling this base wage, we obtain a fully loaded median wage rate of \$37.76 per hour. The total cost to all respondents for this collection of information is estimated to be \$64,109.72. We assume an administrative assistant will respond to the survey invitation.

¹ https://www.bls.gov/oes/current/naics4_325600.htm, accessed March 2018.

Multiplying the fully loaded wage by the total burden estimate of 71.84 hours, we estimate that the respondent costs for the invitation will be \$2,712.68.

For the sake of calculating cost to respond to the survey, we assume management (e.g., a plant manager) will complete the survey. The May 2016 median hourly wage rate for U.S General Operations and Managers (Occupation Code 11-1021) in the Soap, Cleaning Compound, and Toilet Preparation Manufacturing industry (NAICS code 325600) is \$54.43. Doubling this base wage, we obtain a fully loaded median hourly wage rate of \$108.86 per hour. Multiplying the fully loaded hourly wage rate by the total burden estimate of 564 hours, we estimate that the respondent costs to complete the surveys will be \$61,397.04. These estimates are presented in Table 2.

Table 2. --Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Fully Loaded Hourly Wage Rate	Total Respondent Costs
Administrative Assistant (Occupation Code 43-6010)	71.84	\$37.76	\$2,712.68
Plant Manager (Occupation Code 11-1021)	564	\$108.86	\$61,397.04
Total			\$64,109.72

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate the total cost of the information collection to the Federal Government is \$328,134. This includes the value of a task order to design and test the survey instrument, collect and analyze the data, and create a written report.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Following OMB approval, the data collection contractor will collect the information and prepare the deliverables in accordance with the contract requirements. The schedule is shown in Table 3.

Table 3: Project Schedule

Date	Activity	Audience
2 weeks after receipt of OMB	Survey administration	Not

approval of collection of information		applicable
6 months after start of survey administration	Interim draft final report and data files	FDA
4 weeks after receipt of FDA comments on interim draft final report and data files	Draft final report and data files	FDA
2 weeks after receipt of FDA comments on draft final report and data files	Final report and data files	FDA

The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. The exact timing and nature of any such dissemination has not been determined, but may include presentations and articles at trade and academic conferences, publications, and internet postings.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB approval and expiration date will be displayed on all materials associated with the study.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.