FOOD AND DRUG ADMINISTRATION

Cosmetic Labeling Regulations

0910-0599

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the Fair Packaging and Labeling Act (the FPLA) require that cosmetic manufacturers, packers, and distributors disclose information about themselves or their products on the labels or labeling of their products. Sections 201, 301, 502, 601, 602, 603, 701, and 704 of the FD&C Act (21 U.S.C. 321, 352, 361, 362, 363, 371, and 374) and sections 4 and 5 of the FPLA (15 U.S.C. 1453 and 1454) provide authority to the Food and Drug Administration (FDA or we) to regulate the labeling of cosmetic products. Failure to comply with the requirements for cosmetic labeling may render a cosmetic adulterated under section 601 of the FD&C Act or misbranded under section 602 of the FD&C Act.

Under the FD&C Act and the FPLA, cosmetic labels must bear a statement of identity of the cosmetic product, the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the net quantity of contents. These requirements apply both to cosmetics that are marketed as consumer commodities (offered for retail sale) and to cosmetics that are manufactured and sold "for professional use only."

Under the FPLA, cosmetic products that are offered for retail sale must bear a declaration of the name of each ingredient in descending order of predominance, except that a fragrance or flavor may be listed as "fragrance" or "flavor." In addition, ingredients present at a concentration of less than 1 percent and color additives may be grouped at the end of the ingredient statement. The requirement for declaration of ingredients does not apply to non-retail professional-use-only products unless such declaration is specifically required by applicable regulations.

FDA's cosmetic labeling regulations are codified at 21 CFR part 701. The information collection provisions are as follows:

21 CFR 701.3 – Third Party Disclosure – Designation of Ingredients

Requires the label of a cosmetic product to bear a declaration of the ingredients in descending order of predominance.

21 CFR 701.11 – Third Party Disclosure – Identity Labeling

Requires the principal display panel of a cosmetic product to bear a statement of the identity of the product.

21 CFR 701.12 – Third Party Disclosure – Name and Place of Business of Manufacturer, Packer, or Distributor

Requires the label of a cosmetic product to specify the name and place of business of the manufacturer, packer, or distributor.

21 CFR 701.13 – Third Party Disclosure – Declaration of Net Quantity of Contents

Requires the label of a cosmetic product to declare the net quantity of contents of the product.

Accordingly, FDA is requesting OMB approval for the information collection provisions found in the regulations.

2. Purpose and Use of the Information Collection

The information required to be disclosed in FDA's cosmetic labeling regulations is used by consumers of cosmetic products when evaluating, purchasing, and using the products. FDA uses the information to evaluate cosmetic products currently on the market and to verify compliance with the requirements for labeling cosmetic products.

Description of Respondents: Respondents to this collection of information include cosmetic manufacturers, packers, and distributors. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

Cosmetic product manufacturers, packers, and distributors may use any available information technology to develop their product labels. However, there is currently no information technology that establishments can use as a substitute for conventional product labels to deliver the necessary information to consumers. Thus, FDA estimates that approximately 90% of respondents will use information technology to develop their product labels, but also estimates that none of the respondents (0%) will actually use electronic product labels for their products.

4. Efforts to Identify Duplication and Use of Similar Information

   There is no duplication of efforts to collect this information by other federal agencies. FDA is the only federal agency that requires the specified information to appear on the label or labeling of every cosmetic product that the agency regulates.

5. Impact on Small Businesses or Other Small Entities

   FDA estimates that approximately 80% of the establishments that will be affected by this information collection request probably qualify as small businesses with sales under $5,000,000 per year.

   FDA has set requirements for labeling cosmetic products to the minimum requirements that comply with the appropriate provisions of the FD&C Act and the FPLA. In most cases, the information that FDA requires establishments, including small businesses, to disclose, is information that is available to those establishments in the normal course of doing business.

6. Consequences of Collecting the Information Less Frequently

   Respondents will update the required labeling information on an occasional basis, associated with the development and marketing of their products, as required by the FD&C Act and the FPLA. If the information was not collected, that is, if FDA did not require this information to appear on the label or labeling of every cosmetic product that the agency regulates, then the agency's ability to enforce the relevant provisions of the FD&C Act and the FPLA would be nullified. In this case, consumers would be unable to obtain from cosmetic product labels the information they need to evaluate and use cosmetic products.

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

   There are no special circumstances associated with 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), in the Federal Register of May 23, 2017 (82 FR 23576), FDA published a 60-day notice requesting public comment on the proposed extension of this collection of information. One comment was received which described ingredients used in the creation of cosmetics but was not PRA-related and therefore was not addressed by FDA in its 30-day notice.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

None of the information required to appear on the label or labeling of cosmetic products that the agency regulates is confidential.

11. Justification for Sensitive Questions

This information collection does not ask questions of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1—Estimated Annual Third Party Disclosure Burden[1]

21 CFR Section/Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
701.3/Ingredients in order of predominance	1,518	21	31,878	1	31,878
701.11/Statements of identity	1,518	24	36,432	1	36,432
701.12/Name and place of business	1,518	24	36,432	1	36,432
701.13/Net quantity of contents	1,518	24	36,432	1	36,432
Total					141,174

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

The hour burden is the additional or incremental time that establishments need to design and print labeling that includes the following required elements: a declaration of ingredients in decreasing order of predominance; a statement of the identity of the product; a specification of the name and place of business of the establishment; and a declaration of the net quantity of contents. These requirements increase the time establishments need to design labels because they increase the number of label elements that establishments must take into account when designing labels. These requirements do not generate any recurring burden per label because establishments must already print and affix labels to cosmetic products as part of normal business practices.

The estimated annual third party disclosure is based on data available to the agency, our knowledge of and experience with cosmetic labeling, and our communications with industry. We estimate there are 1,518 cosmetic product establishments in the United States. We calculate label design costs based on stockkeeping units (SKUs) because each SKU has a unique product label. Based on data available to the agency and on communications with industry, we estimate that cosmetic establishments will offer 94,800 SKUs for retail sale in 2017. This corresponds to an average of 62 SKUs per establishment.

One of the four provisions that we discuss in this information collection, § 701.3, applies only to cosmetic products offered for retail sale. However, the other three provisions, §§ 701.11, 701.12, and 701.13, apply to all cosmetic products, including non-retail professional-use-only products. We estimate that including professional-use-only cosmetic products increases the total number of SKUs by 15 percent to 109,020. This corresponds to an average of 72 SKUs per establishment.

Finally, based on the agency's experience with other products, we estimate that cosmetic establishments may redesign up to one-third of SKUs per year. Therefore, we estimate that the number of disclosures per respondent will be 21 (31,878 SKUs) for § 701.3 and 24 each (36,432 SKUs) for §§ 701.11, 701.12, and 701.13.

We estimate that each of the required label elements may add approximately 1 hour to the label design process. We base this estimate on the burden hours the agency has previously estimated for food, drug, and medical device labeling and on the agency's knowledge of cosmetic labeling.

12b. Annualized Cost Burden Estimate

We estimate the annualized burden hour cost to respondents for this collection of information to be approximately $10,785,693.60. We estimate that the label design process will involve an employee making an average wage similar that of a Federal government employee at the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2017, which is $38.20 per hour. To account for overhead, this cost is increased by 100 percent, which is $76.40 per hour. Thus, the annual wage cost imposed by this collection of information is approximately $10,785,693.60 (141,174 hours x $76.40 per hour).

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Label Design Process	141,174	$76.40	$10,785,693.60

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 collection.

14. Annualized Cost to the Federal Government

As part of FDA's responsibility to enforce the provisions of the FD&C Act and the FPLA, the agency conducts the Cosmetics Compliance Program to evaluate cosmetic products for compliance with the labeling requirements. Under this program, FDA's field offices carry out investigations, inspections, sample collections, sample analyses, and other compliance activities, and FDA's headquarters provides guidance for field office activities. In addition, FDA provides advice to representatives of cosmetic establishments and start-up businesses regarding the labeling requirements for cosmetic products. We estimate that the agency needs six professional staff persons per year (12,480 hours) to review compliance and regulatory activities related to cosmetic labeling. Using an hourly cost to the agency of $38.20 per hour (the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2017, increased by 100 percent, which is $76.40 to account for overhead), we estimate the annual cost to the Federal government to be $953,472 (12,480 x 76.40 per hour).

15. Explanation for Program Changes or Adjustments

This information collection remains unchanged. At the same time, we have revised the IC list appearing at www.reginfo.gov by consolidating the previously itemized regulatory provisions. We believe this will assist the reader by more easily identifying the summary of cumulative fluctuations for the collection. At the same time, readers may still view estimated burden associated with individual provisions by referring to the agency's 60-day and 30-day notices and in the burden tables found in Q.12: *Estimates of Annualized Burden Hours and Costs* of this supporting statement.

16. Plans for Tabulation and Publication and Project Time Schedule

The information from this collection will not be published.

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.