Cosmetic Labeling Regulations

OMB Control No. 0910-0599

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Federal Food, Drug, and Cosmetic Act (the FFDCA) 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, 502, 601, 602, 603, 701, and 704 of the FFDCA (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) 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 FFDCA or misbranded under section 602 of the act.

Under the FFDCA and the FPLA, cosmetic labels must bear a statement of the 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 use only by professionals (non-retail professional-use-only products or salon products).

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 published in 21 CFR part 701. Four of the cosmetic labeling regulations have information collection provisions.

We request the extension of OMB approval for the following collection of information requirements:

21 CFR 701.3 – Third Party Disclosure

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

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

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

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

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 none of the respondents (0%) will use electronic product labels.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplication of efforts to collect this information by other federal agencies. The 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 FFDCA 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.

FDA aids small businesses in complying with the cosmetic labeling requirements through the agency's Regional Small Business Representatives and through the administrative and scientific staffs within the Agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

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 FFDCA 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 FFDCA 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 March 16, 2010 (75 FR 12546), FDA published a 60-day notice requesting public comment on the proposed extension of this collection of information. FDA received one letter, containing multiple comments, in response to the notice. One comment expressed strong support for the labeling of cosmetics. Additional comments were outside the scope of the four collection of information topics on which the notice solicits comments.

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

The estimated total annual hour burden imposed by this collection of information is 141,174 hours. FDA estimates the total annual hour burden, which is the annual third party disclosure burden, as follows.

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.

According to the 2001 census, there are 1,518 cosmetic product establishments in the United States (U.S. Census Bureau, http://www.census.gov/epcd/susb/2001/us/US32562.HTM). FDA calculates 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, FDA estimates that cosmetic establishments will offer 94,800 SKUs for retail sale in 2010. This corresponds to an average of 62 SKUs per establishment.

One of the four provisions that FDA discusses 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. FDA estimates 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, FDA estimates that cosmetic establishments may redesign up to one-third of SKUs per year. Therefore, FDA estimates that the annual frequency of response will be 21 (31,600 SKUs) for § 701.3 and 24 each (36,432 SKUs) for §§ 701.11, 701.12, and 701.13.

FDA estimates that each of the required label elements may add approximately 1 hour to the label design process. FDA bases this estimate on the hour burdens the agency has previously estimated for food, drug, and medical device labeling and on the agency's knowledge of cosmetic labeling. Therefore, FDA estimates that the total hour burden on members of the public for this information collection is 141,174 hours per year.

FDA's estimate of the total annual hour burden, which is the annual third party disclosure burden, is summarized in Table 1.

Table 1—Estimated Annual Third Party Disclosure Burden

21 CFR Section	No. of Respondents	Annual Frequency of Disclosure	Total Annual Disclosures	Hours per Disclosure	Total Hours
701.3	1,518	21	31,878	1	31,878
701.11	1,518	24	36,432	1	36,432
701.12	1,518	24	36,432	1	36,432
701.13	1,518	24	36,432	1	36,432
Total					141,174

12 b. Annualized Cost Burden Estimate

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $10,130,646.24. FDA estimates 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 2010, which is $35.88 per hour. To account for overhead, this cost is increased by 100 percent, which is $71.76 per hour. Thus, the annual wage cost imposed by this collection of information is approximately $10,130,646.24 (141,174 hours x $71.76 per hour).

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. This collection of information requires establishments to have whatever equipment they need to obtain the necessary information, produce labels, and affix them to cosmetic products. However, establishments already need this equipment as part of normal business practices relating to cosmetic products.

14. Annualized Cost to the Federal Government

As part of FDA's responsibility to enforce the provisions of the FFDCA 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 information that the agency requires to appear on cosmetic labels and the agency conducts other compliance and regulatory activities related to cosmetic labeling. FDA estimates that the agency needs six professional staff persons per year (12,480 hours) to perform compliance and regulatory activities related to cosmetic labeling. Using an hourly cost to the agency of $71.76 per hour (the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2010, increased by 100 percent to account for overhead), FDA estimates the annual cost to be $895,564,80.

15. Explanation for Program Changes or Adjustments

Although burden estimate remained unchanged there was an increase in the number of responses reported as 72,864. **The reason in response to OMBs inquiry**: In 2007, this ICR was submitted with only 2 ICs. In 2010 this ICR was submitted (changed) with the correct number of 4 ICs. Thus, in 2007, there was a technical error in ICRAS with respect to the number of ICs , which affected how the system calculated the total annual responses; instead of reflecting 141,174 annual responses , the error resulted in only 63,310total annual responses being reported, a deficit of 72,864 responses. Please note that the estimate of the burden hours (141,174) was correct . The increase in the number of responses in ICRAS in 2010(increase of 72,864 responses) corrects the 2007 error, bringing the total annual responses up to the correct estimate of 141,174.

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.