SUPPORTING STATEMENT

Cosmetic Labeling Regulations

21 CFR §§ 701.3 and 701.11 - 701.13

A. JUSTIFICATION

1. Need and Legal Basis

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 502, 601, 602, 603, 701, and 704 of the FFDCA (21 U.S.C. 352, 361, 362, 363, 371, and 374) (Attachment A) and §§ 4 and 5 of the FPLA (15 U.S.C. 1453 and 1454) (Attachment B) 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 § 601 of the FFDCA or misbranded under § 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 (Attachment C). Four of the cosmetic labeling regulations have information collection provisions. Section 701.3 requires the label of a cosmetic product to bear a declaration of the ingredients in descending order of predominance. Section 701.11 requires the principal display panel of a cosmetic product to bear a statement of the identity of the product. Section 701.12 requires the label of a cosmetic product to specify the name and place of business of the manufacturer, packer, or distributor. Section 701.13 requires the label of a cosmetic product to declare the net quantity of contents of the product.

FDA's cosmetic labeling regulations were published in the Federal Register on March 15, 1974 (39 FR 10054 at 10056) and subsequently amended, most recently on March 17, 1999 (64 FR 13254 at 13297).

2. Information Users

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.

3. Improved Information Technology

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.

4. Duplication of Similar Information

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

5. Small Businesses

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 administrative and scientific staffs. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Less Frequent Collection

If the information was not collected, that is, tf 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

This information collection is not associated with any special circumstances.

8. Federal Register Notice / Outside Consultation

In accordance with the Paperwork Reduction Act and OMB's regulations at 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of January 18, 2006 (71 FR 2947) (Attachment D). No comments were received. FDA's cosmetic labeling regulations, as published in the Federal Register on March 15, 1974 (39 FR 10054 at 10056) and subsequently amended, most recently on March 17, 1999 (64 FR 13254 at 13297), remain unchanged by the notice. This notice does not represent any new regulatory initiative.

9. Payment / Gift to Respondent

The cosmetic labeling regulations do not provide for any payments or gifts to respondents.

10. Confidentiality

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

11. Sensitive Questions

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

12. Burden Estimate (Total Hours and Wages)

(a) Estimate of total annual hour burden

The estimated total annual hour burden imposed by this collection of information is 140,620 hours. FDA estimates the total annual hour burden, which is the annual reporting 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 2005. 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 (36,340 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 140,620 hours per year.

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

Table 1—Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
701.3	1518	21	31,878	1.00	31,878
701.11	1518	24	36,342	1.00	36,342
701.12	1518	24	36,342	1.00	36,342
701.13	1518	24	36,342	1.00	36,342
Total					141,174

(b) Estimate of total annual cost burden

FDA estimates that the total annual cost burden imposed by this collection of information will be approximately $8,437,200 based on 141,174 burden hours at an hourly industry cost of $60 per hour (wages plus benefits and overhead equivalent to a GS-12 salary).

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs or operating and 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. Cost to 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 $60 per hour (GS-12 salary wages plus benefits and overhead), FDA estimates the annual cost to be $748,800.

15. Program or Burden Changes

This is an existing information collection in use without an OMB control number. FDA's cosmetic labeling regulations in 21 CFR Part 701 require that cosmetic manufacturers, packers, and distributors label their products with a list of ingredients in descending order of predominance, a statement of the identity of the product, the establishment's name and place of business, and the net quantity of contents. FDA's cosmetic labeling regulations were published in the Federal Register on March 15, 1974 (39 FR 10054 at 10056) and subsequently amended, most recently on March 17, 1999 (64 FR 13254 at 13297). Sometime subsequent to the amendments of 1999, CFSAN staff noticed that the labeling regulations had information collection provisions for which there was no OMB approval. This was reported in the 2006-2007 Information Collection Budget.

16. Publication and Tabulation Dates

FDA does not plan or anticipate any comprehensive tabulation of the data in this information collection.

17. Display of OMB Approval Date

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 statement identified in Item 19 of OMB Form 83-I, "Certification for Paperwork Reduction Act Submissions."

B. COLLECTIONS OF INFORMATION USING STATISTICAL METHODS

This information collection does not use statistical methods.