

**SUPPORTING STATEMENT FOR
COSMETIC PRODUCT VOLUNTARY REPORTING PROGRAM
OMB No. 0910-0030**

SECTION A - Justification

1. Necessity for the Information Collection

Under the Federal Food, Drug, and Cosmetic Act as amended (the act), cosmetic products that are adulterated under section 601 (21 U.S.C. 361) or misbranded under section 602 (21 U.S.C. 362) cannot legally be distributed in interstate commerce (**Attachment A**). **The act does not authorize the Commissioner of the Food and Drug Administration to require mandatory registration of cosmetic product formulations, although such authority would lead to more efficient enforcement of the act.**

The FDA's Cosmetic Product Voluntary Reporting Program provides for the voluntary filing of cosmetic product ingredient statements and for the discontinuance of commercial distribution of a cosmetic product formulation. FDA established the program in response to petitions by the Cosmetic, Toiletry, and Fragrance Association, Inc. (CTFA) and issued regulations for the program in final rules published in the Federal Registers of April 11, 1972 (37 FR 7151) and October 17, 1973 (38 FR 28914). In response to another petition by CTFA and comments to a proposed rule (55 FR 42993, October 25, 1990), FDA modified the program by ending the reporting of semi-quantitative ingredient information, integrating information on raw materials into its cosmetic product ingredient statements, and ending the voluntary reporting of cosmetic product experiences (57 FR 3128, January 28, 1992; 62 FR 43071, August 12, 1997).

FDA requests OMB approval for use of the following forms by participants in the Cosmetic Product Voluntary Reporting Program (Attachment B). The instructions for filing the forms are included in Attachment C.

**FDA 2512 - Cosmetic Product Ingredient Statement
FDA 2512a - Cosmetic Product Ingredient Statement (continuation of FDA 2512)
FDA 2514 - Notice of Discontinuance of Commercial Distribution of Cosmetic Product**

The regulations that describe the information collection requirements for this program are listed in 21 CFR part 720 (Attachment A) and are summarized as follows:

21 CFR 720.4 Information requested about cosmetic products.

This regulation describes how to list ingredients on Forms FDA 2512 and FDA 2512a for a cosmetic product and gives product categories that should be cited to indicate the product's intended use.

21 CFR 720.6 Amendments to statement.

Amended Forms FDA 2512 and FDA 2512a should be submitted within 60 days after the product is entered into commercial distribution if an ingredient or product brand name is changed from that previously filed or within a year if other changes are made. Form FDA 2514 should be submitted within 180 days after discontinuance of commercial distribution of a registered product.

21 CFR 720.8 Confidentiality of statements.

Requests for confidentiality will be subject to the provisions of this regulation and to certain provisions of 21 CFR part 20.

2. Uses of the Information

FDA uses the information provided under the Cosmetic Product Voluntary Reporting Program as input for a computer-based information storage and retrieval system. The voluntarily filed cosmetic product formulations provide FDA with the best information available about cosmetic product formulations, ingredients, and their frequency of use; businesses engaged in the manufacture and/or distribution of

cosmetics; and approximate rates of product discontinuance and formula modifications. FDA's database also lists cosmetic products containing ingredients suspected to be carcinogenic or otherwise deleterious to the public health. The information assists FDA scientists in evaluating alleged injuries and adverse reactions due to the use of cosmetics and in defining and planning analytical and toxicological studies pertaining to cosmetics.

FDA shares nonconfidential information from its files on cosmetics with consumers, medical professionals, and industry. Through Freedom of Information Act requests, consumers obtain information about which products do or do not contain a specified ingredient and about the levels at which certain ingredients are typically used. Dermatologists use FDA files to cross-reference allergens found in patch test kits with cosmetic ingredients. CTFA has obtained FDA data on the frequency of use of cosmetic ingredients to select ingredients for its review.

3. Use of Improved Information Technology

The FDA continually seeks ways to reduce reporting burden through advances in information technology. Presently, Forms FDA 2512 and FDA 2512a may be submitted by letter, by computer-printed facsimile, by computer diskette, or on magnetic tape. Form FDA 2514 can be submitted by letter or by computer diskette. The FDA is working on establishing a personal computer format for accepting cosmetic product formulation data. Submission capability by this medium will reduce the reporting burden for respondents and the FDA.

4. Efforts to Avoid Duplication and Unavailability of Similar Information

To the best of our knowledge, no other government agency is engaged in the collection of these data. No other available databases contain the information collected from Forms FDA 2512, FDA 2512a, and FDA 2514.

5. Methods to Minimize Burden on Small Businesses

This information collection may include small businesses. However, the use of Forms FDA 2512, FDA 2512a, and FDA 2514 is expected to increase with the size of the reporting firm, the number of products manufactured, and the turnover of product lines. FDA aids small businesses in complying with its requirements through the Office of Small Manufacturers Assistance and through its administrative and scientific staffs.

6. Consequences if Data Were Not Collected or Collected Less Frequently

The data in original cosmetic product formulation statements and notices of discontinuance are submitted only once and therefore cannot be collected less frequently. The data in amended cosmetic product formulation statements are submitted only if a manufacturer changes a cosmetic product formulation.

7. Special Circumstances Involving Information Collection

There are no special circumstances involving this information collection. No comprehensive tabulation of the data is planned or anticipated. Participation in the program and the submission of data are voluntary. After participants submit cosmetic product formulation statements to the FDA using Forms FDA 2512 and FDA 2512a, they are requested to submit additional information only if a formulation is changed or discontinued. The forms include copies for the participants to retain following their submissions.

8. Consistency with 5 CFR 1320.8(d).

In accordance with the Paperwork Reduction Act of 1995, FDA published a 60-day notice in the Federal Register of August 9, 1999 (61 FR 43188) (Attachment D), in which the agency requested comments on the Cosmetic Product Voluntary Reporting Program. One comment was received in support of the continuation of the program.

9. Payment or Gift to Respondents

There are no payments or gifts provided to respondents.

10. Assurance of Confidentiality

In accordance with 21 CFR 720.8, respondents may request that entire formulations, combinations of ingredients, or single ingredients be accepted and maintained in confidence on the grounds that public disclosure of such information would reveal a trade secret or confidential commercial information as defined in 21 CFR 20.61. Only one or two cosmetic product ingredient statements containing confidentiality requests are received annually. Pending FDA's decision whether or not to grant the request, the agency holds a submission separately and does not make it available for public disclosure. If FDA denies the request, the respondent may submit the ingredient data on a non-confidential basis or may withdraw the submission in accordance with 21 CFR 20.44. If FDA grants the request, the agency maintains the cosmetic product formulation information in confidence in accordance with 21 CFR 20.111.

Each confidential ingredient in a submission is so designated and, in order to ensure protection from accidental disclosure or unauthorized access, is subject to the following security measures:

- **Combination locks are installed on the two doors leading to the secured area where records are received and stored. The combination is known only to the FDA personnel working on the program in the secured area.**
- **At least one authorized person is in the secured area at all times during working days, including lunch periods and break periods. On rare occasions when this is impractical, the doors to the secured area are shut and locked.**
- **Doors to the secured area are shut and locked at the end of each working day by authorized personnel. The night shift cleaning personnel do not have access to the secured area.**
- **All data processing forms are entered by Office of Cosmetics and Colors (OCAC) personnel and, therefore, do not leave the secured area until filed in a secured file room.**
- **Access to the files in the secured area is permitted only to authorized FDA personnel.**
- **All computer printouts are generated under security access release by OCAC personnel within the secured working area.**
- **Any information requested by FDA personnel outside OCAC, or by the public in FOIA requests, must be authorized by the Division Director, Division of Programs and Enforcement Policy, OCAC, before such information is released.**

11. Sensitive Questions

The Cosmetic Product Voluntary Reporting Program forms do not contain questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered to be private or of a sensitive nature.

12. Respondent Hour Burden and Annualized Hour Burden Cost

a. Hour burden.

The burden for this information collection is 1,662 hours. The burden is based on estimates by FDA administrative and scientific staffs from past experience and from discussions with respondents during routine communications. The actual time required for each submission will vary in relation to the size of the company and the breadth of its marketing activities.

The following table summarizes the estimated annual reporting burden:

Estimated Annual Reporting Burden						
21 CFR Section	Form No.	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Burden Hours
720.4	FDA 2512 FDA 2512a	550	4.2	2,310	0.50	1,155
720.6	FDA 2512 FDA 2512a	550	1.4	770	0.33	254
720.6	FDA 2514	550	4.5	2,500	0.10	250
720.8		2	1.0	2	1.50	3
Total		552		5,582		1,662

b. Annualized hour burden cost to respondent.

The total annual hour burden hour cost to respondents is approximately \$39,888. The cost is estimated using an hourly wage of \$24 per hour, so that 1,662 burden hours times \$24 per hour equals \$39,888.

13. Respondent Cost Burden

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

14. Estimated Costs to Federal Government

FDA estimates that 1.75 professional staff persons per year (3,640 hours) are needed to process submitted forms and maintain computer files, at a cost of \$87,955 per year. This estimate is based on a salary of \$50,260 per year (\$24 per hour) for professional staff members at the average grade level of GS-12, step 1. FDA distributes annually approximately 6,000 preprinted Forms FDA 2512; 9,000 preprinted Forms FDA 2512a; and 2,000 preprinted Forms FDA 2514. The cost of the 3-part preprinted forms is approximately \$0.05 each, for a total cost of \$850. FDA estimates that computer costs are \$3000 annually. FDA estimates the total annual cost to the federal government for the **Cosmetic Product Voluntary Reporting Program** is \$91,805.

15. Changes in Burden

There are no changes in the hour burden for this collection of information. The **Cosmetic Product Voluntary Reporting Program** was suspended during FY 1998 because of a lack of funding and was reinstated at the beginning of FY 1999. Participation returned to the previous level, and FDA estimates the annual hour burden to remain the same as that presently on file with the OMB.

There is a 9% increase in the annualized hour burden cost to respondents, due to estimated cost of living increases.

16. Statistical Analysis, Publication Plans, and Schedule

No comprehensive tabulation of the data is planned or anticipated.

17. Displaying of OMB Expiration Date

The agency is not seeking to not display the expiration date for OMB approval of the information collection.

18. Exceptions to the Certification Statement - Item 19

There are no exceptions to the certification statement identified in Item 19 of OMB Form 83-I, "Certification for Paperwork Reduction Act Submissions".

SECTION B - Collections of Information Employing Statistical Methods

The collections of information using Forms FDA 2512, FDA 2512a, and Form FDA 2514 do not employ statistical methods.

Attachment A
Statutes and Regulations

Attachment B

Form FDA 2512, Form FDA 2512a, and Form FDA 2514

Attachment C

Instructions for Voluntary Filing of
Cosmetic Product Formulations

Attachment D

Federal Register of August 29, 1996 (61 FR 45431)