VOLUNTARY COSMETIC REGISTRATION PROGRAM

OMB No. 0910-0030

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Federal Food, Drug, and Cosmetic Act (the act) provides FDA with the authority to regulate cosmetic products in the United States. Cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, the agency has developed the Voluntary Cosmetic Registration Program (VCRP). In 21 CFR part 720, FDA requests that firms that manufacture, pack, or distribute cosmetics file with the agency an ingredient statement for each of their products. Ingredient statements for new submissions (§§ 720.1 through 720.4) are reported on Form FDA 2512, "Cosmetic Product Ingredient Statement," and on Form FDA 2512a, a continuation form. Amendments to product formulations (§§ 720.3, 720.4, and 720.6) also are reported on Forms FDA 2512 and FDA 2512a. When a firm discontinues the commercial distribution of a cosmetic, FDA requests that the firm file Form FDA 2514, "Discontinuance of Commercial Distribution of Cosmetic Product Formulation" (§§ 720.3 and 720.6).

We request OMB approval of Forms FDA 2512, FDA 2512a, and FDA 2514 and the reporting burdens contained in the following citations:

21 CFR 720.1 Who should file.—Manufacturers, packers, and distributors of cosmetic products are requested to file Forms FDA 2512 and FDA 2512a, whether or not the cosmetic product enters interstate commerce. This request extends to foreign manufacturers, packers, and distributors of cosmetic products exported for sale in the U.S.

21 CFR 720.2 Times for filing.—Forms FDA 2512 and FDA 2512a should be filed within 60 days after the beginning of commercial distribution of any cosmetic product.

21 CFR 720.3 How and where to file.—Forms FDA 2512, FDA 2512a, and FDA 2514 should be mailed to the FDA address specified in this regulation.

21 CFR 720.4 Information requested about cosmetic products.—Form FDA 2512 requests information on the name and address of the manufacturer, packer, or distributor, brand name(s), and product category or categories of the cosmetic product being filed. Form FDA 2512a requests information on the ingredients in the cosmetic product. Forms should be signed by an authorized representative of the firm.

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 filed product.

21 CFR 720.8 Confidentiality of statements.—Cosmetic product filers may request confidentiality of the identity of a cosmetic ingredient if such information is a trade secret or confidential commercial or financial information as defined in 21 CFR 20.61. Requests for confidentiality are subject to the provisions of this regulation and 21 CFR 20.111.

2. Purpose and Use of the Information Collection

FDA places cosmetic product filing information in a computer data base and uses the information for evaluation of cosmetic products currently on the market. Because filing of cosmetic product formulations is not mandatory, voluntary filings provide FDA with the best information available about cosmetic product ingredients and their frequency of use, businesses engaged in the manufacture and distribution of cosmetics, and approximate rates of product discontinuance and formula modifications. The information assists FDA scientists in evaluating reports of alleged injuries and adverse reactions from the use of cosmetics. The information also is used in defining and planning analytical and toxicological studies pertaining to cosmetics.
Information from the database is releasable to the public under FDA compliance with the Freedom of Information Act. FDA shares nonconfidential information from its files on cosmetics with consumers, medical professionals, and industry.

3. Use of Improved Information Technology and Burden Reduction

FDA's online filing system, intended to make it easier to participate in the VCRP, was made available industry-wide on December 1, 2005. The online filing system is available on FDA's VCRP Web site at http://www.cfsan.fda.gov/~dms/cos-regn.html. The online filing system contains the electronic versions of Forms FDA 2512, 2512a, and 2514, which are collectively found within the electronic version of Form FDA 2512. The agency strongly encourages electronic filing of Form FDA 2512 because it is faster and more convenient. A filing facility will receive confirmation of electronic filing by e-mail. Submission of the paper versions of Forms FDA 2512, 2512a, and 2514 remains an option as described in http://www.cfsan.fda.gov/~dms/cos-reg2.html. However, due to the high volume of online participation, the VCRP is allocating its limited resources primarily to electronic filings.

4. Efforts to Identify Duplication and Use of Similar Information

To the best of FDA's knowledge, no other federal government agency is engaged in the collection of this information.

5. Impact on Small Businesses or Other Small Entities

This information collection will not have a significant economic impact on 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 submitting requested information through the agency's Regional Small Business Representatives and through the administrative and scientific staffs within the agency. FDA's Small Business Guide is available on its website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Original cosmetic product ingredient statements and notices of discontinuance are submitted only once and therefore cannot be collected less frequently. Amended cosmetic product ingredient statements are submitted only if a manufacturer changes a cosmetic product formulation.

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

There are no special circumstances involving this information collection.

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

In the Federal Register of September 17, 2008 (73 FR 53877), FDA published a 60-day notice requesting public comment on the collection of information associated with the Voluntary Cosmetic Registration Program. FDA received two letters in response to the notice, each containing one or more comments. One comment suggested that FDA make the voluntary cosmetic registration program mandatory. FDA responds that it has no statutory authority to require mandatory cosmetic product reporting. The remaining comments received were not responsive to the comment request on the four specified aspects of the collection of information. These non-responsive comments will not be addressed in this document.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Authorized personnel in FDA's Office of Cosmetics and Colors receive, evaluate, and store all information filed on Forms FDA 2512, FDA 2512a, and FDA 2514 in secured work areas. When not being evaluated, the forms are stored in locked file cabinets in a dedicated locked file room. As part of the evaluation, authorized personnel add the filing information to a computer data base. Security of the computer data base meets all mandated Department of Health and Human Services requirements. Access to the forms, file room, and computer data base is limited to authorized personnel.

Under 21 CFR 720.8, cosmetic product ingredient filers may request confidentiality of the identity of a cosmetic ingredient if such information is a trade secret or confidential commercial or financial information as defined in 21 CFR 20.61. Requests for confidentiality are subject to the provisions of 21 CFR 20.111 and 21 CFR 20 subparts D and E. If FDA grants the request, the information is not available for public disclosure.

FDA shares non-confidential information from its files on cosmetics with consumers, medical professionals, and the cosmetic industry. Non-confidential information is releasable to the public under FDA compliance with the Freedom of Information Act. All release of information must be authorized by management staff in FDA's Office of Cosmetics and Colors and is processed by the agency's Division of Freedom of Information.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

FDA estimates the burden of this collection of information as follows:

Table 1. – Estimated Annual Reporting Burden[1]

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
720.1 through 720.4 (new submissions)	2512[2]	141	31	4371	.33	1442
720.4 and 720.6 (amend-ments)	2512	109	7	763	.17	130
720.3, 720.6 (notices of	2512	55	41	2255	.1	226

dis-continuance)						
720.8 (requests for confiden-tiality)		1	1	1	1.5	1.5
Total						1800

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

[2] The term "Form FDA 2512" refers to both the paper Forms FDA 2512, 2512a, and 2514 and electronic Form FDA 2512 in the electronic system known as the Voluntary Cosmetic Registration Program, which is available at http://www.cfsan.fda.gov/~dms/cos-regn.html.

The estimated number of respondents is based on submissions received from fiscal years FY 2005 to FY 2007. The estimated time required for each submission is based upon information from cosmetic industry personnel and FDA experience entering data submitted on paper Forms 2512, 2512a, and 2514**.**

Estimated Annualized Cost for the Burden Hours

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $119,445. FDA estimates a respondent's average wage to be that of a Federal government employee at the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2008, which makes the annual wage cost for completion and submission approximately $59,722.70 (1,786.5 hours x $33.43 per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondent $119,445.40, rounded to $119,445.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to Federal Government

FDA estimates that 2.8 professional staff persons per year (5,824 hours) are needed to process submitted forms and maintain computer files. Using an hourly wage of $33.43 per hour, FDA estimates the annual staff cost to be $194,696.32 (5,824 hours x $33.43 per hour). FDA estimates total direct and indirect costs (overhead) to be $21,200. Thus, FDA estimates the total annual cost to FDA for this information collection to be $215,896.32 ($194,696.32 + $21,200).

15. Explanation for Program Changes or Adjustments

The increase in total annual responses is due to increased participation by cosmetic companies, because of a renewed industry commitment to the program, and implementation of the online filing system on December 1, 2005. The decrease in hours per response is due to the ease of online filing.

16. Plans for Tabulation and Publication and Project Time Schedule

No comprehensive statistical reporting, tabulation, or publication of the data are planned.

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

FDA is not seeking not to display the OMB approval date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

N/A