SUPPORTING STATEMENT

VOLUNTARY REGISTRATION OF COSMETIC PRODUCT ESTABLISHMENTS

OMB No. 0910-0027

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Federal Food**,** Drug**,** and Cosmetic Act (the act) provides FDA with the responsibility for assuring consumers that cosmetic products in the United States are safe and properly labeled. 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, FDA has developed the Voluntary Cosmetic Registration Program (VCRP). In 21 CFR part 710, FDA requests that establishments that manufacture or package cosmetic products register with the agency on Form FDA 2511 entitled "Registration of Cosmetic Product Establishment." The term "Form FDA 2511" refers to both the paper and electronic versions of the form. The electronic version of Form FDA 2511 is available on FDA's VCRP Web site at http://www.cfsan.fda.gov/~dms/cos-regn.html.

We request the extension of OMB approval for the following voluntary collection of information provisions and form:

21 CFR 710.1 -- Reporting

Requests a cosmetic product establishment to register with FDA.

21 CFR 710.4 -- Reporting

Sets forth the requested information. The information requested on Form FDA 2511 includes the name and address of the cosmetic product establishment, all business trading names used by the cosmetic product manufacturer, and the type of business (manufacturer and/or packer).

21 CFR 710.5 -- Reporting

Requests a facility to submit timely updates within 30 days of a change to any information contained in a registration submission.

Form FDA 2511

The term "Form FDA 2511" refers to both the paper and electronic versions of the form.

2. Purpose and Use of the Information Collection

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides FDA with information available about the locations, business trade names, and types of

activity (manufacturing or packaging) of cosmetic product establishments. FDA places the registration information in a computer database and uses the information to generate mailing lists for distributing regulatory information and for inviting firms to participate in workshops on topics in which they may be interested. FDA also uses the information for estimating the size of the cosmetic industry and for conducting onsite establishment inspections. Registration is permanent, although FDA requests that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

3. Use of Improved Information Technology and Burden Reduction

FDA's online registration system, intended to make it easier to participate in the VCRP, was made available industry-wide on December 1, 2005. The agency strongly encourages electronic registration of Form FDA 2511 because it is faster and more convenient. A registering facility will receive confirmation of electronic registration, including a registration number, by e-mail, usually within 7 business days. The online system also allows for amendments to past submissions. Submission of the paper version of Form FDA 2511 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 registrations.

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 does not have a significant economic impact on small businesses. Small businesses usually can complete Form FDA 2511 just by providing the company name and address. FDA aids small businesses in complying with registration requirements through its administrative and scientific staffs. FDA's Small Business Guide is available on FDA's Web site at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Registrations of cosmetic product establishments are submitted only once and therefore cannot be collected less frequently. Amended registrations are submitted occasionally, for example when a cosmetic product establishment site moves or the corporate structure changes.

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

No special circumstances occur when FDA collects this information. Submission of information is voluntary.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the

Federal Register of July 19, 2007 (72 FR 39626). FDA received no comments in response to the notice.

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

None of the information supplied on Form FDA 2511 is confidential. The public and other interested parties may request copies under the provisions of the Freedom of Information Act (FOIA).

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

FDA estimates the burden of this information collection as follows:

Table 1. -–Estimated Annual Reporting Burden[1]

21 CFR Part	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
710	FDA 2511	135	1	135	0.2	27

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

FDA bases its estimate on its review of the registrations received over the past 3 fiscal years. The total annual responses (averaged over fiscal years 2004 through 2006) is 9 times the previous total reported in 2004 (for fiscal years 2000 through 2003) due to increased participation by cosmetic companies, because of a renewed industry commitment to the program, and implementation of the online registration system on December 1, 2005. Due to the ease of online registration, FDA estimates that the hours per response have declined from 0.4 hours to 0.2 hours. Thus, the total estimated hour burden for this information collection is 27 hours, which is 4.5 times the previous level reported in 2004.

Hour Cost Burden

The annual hour cost burden to respondents is approximately $864. FDA estimates the cost by using an hourly wage of $32 per hour (corresponding to a GS-12, step 1, federal government hourly salary); 27 burden hours times $32 per hour equals $864.

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 0.05 professional staff persons per year (100 hours) are needed to process submitted forms and maintain computer files. Using an hourly wage of $32 per hour, FDA estimates the annual staff cost to be $3,200. FDA estimates annual computer costs to be $350. Therefore, FDA estimates the total annual cost to FDA for this information collection is $3,550.

15. Explanation for Program Changes or Adjustments

The change in annual hour burden is an increase of 21 hours over that of the previous approval. The net increase in burden is due to an increase in the number of respondents but a decrease in the hours per response due to the availability of online registration.

The change in annual hour burden cost is an increase of $696 over that of the previous approval. This is due to an increase in total burden hours and an increase in the estimated hourly wage rate applied to the burden hours.

16. Plans for Tabulation and Publication and Project Time Schedule

No comprehensive tabulation of the data is planned or anticipated.

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

FDA has no reason for not displaying the OMB approval date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exception is requested.