

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 2007N-0278]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Registration of Cosmetic Product Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the voluntary registration of cosmetic product establishments with FDA.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Voluntary Registration of Cosmetic Product Establishments—21 CFR Part 710 (OMB Control Number 0910-0027)—Extension

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>. 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.

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides FDA with the best 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.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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

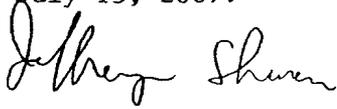
¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

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.

Dated: 7/13/07

July 13, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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