

Dated: September 11, 2008.

Maryam Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0490]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Cosmetic Registration Program

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 collection of information associated with the Voluntary Cosmetic Registration Program.

DATES: Submit written or electronic comments on the collection of information by November 17, 2008.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. 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.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

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 Cosmetic Registration Program—21 CFR Part 720 (OMB Control Number 0910-0030)—Extension

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 part 720 (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). If any of the information submitted on or with these forms is confidential, the firm may submit a request for confidentiality under § 720.8.

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 version 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.

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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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)	FDA 2512 ²	141	31	4371	0.33	1,442
720.4 and 720.6 (amendments)	FDA 2512	109	7	763	0.17	130
720.3, 720.6 (notices of discontinuance)	FDA 2512	55	41	2,255	0.1	226
720.8 (requests for confidentiality)		1	1	1	1.5	1.5
Total						1,800

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 2005 to 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 FDA 2512, 2512a, and 2514. 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: September 10, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0487]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Safety Survey

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 reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a voluntary consumer survey about food safety.

DATES: Submit written or electronic comments on the collection of information by November 17, 2008.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. 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.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

SUPPLEMENTARY INFORMATION:

I. Background

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 reinstatement 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.

Food Safety Survey (OMB Control Number 0910-0345—Reinstatement)

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. The Food Safety Survey is a nationally