TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
310.305(f)	25	1	25	16	400
314.80(i)	642	623	400,000	16	6,400,000
Total					7,088,680

[1]There are no capital costs or operating costs associated with this collection of information. There are maintenance costs of $22,000 annually.

These estimates are based on FDA's knowledge of adverse drug experience reporting, including the time needed to prepare the reports, and the number of reports submitted to the agency.

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: December 9, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29664 Filed 12–15–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0490]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Cosmetic Registration Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 15, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0030. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Voluntary Cosmetic Registration Program—(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.

In the **Federal Register** of September 17, 2008 (73 FR 53877), FDA published a 60-day notice requesting public comment on the information collection

provisions. 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.

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)	FDA 2512[2]	141	31	4,371	.33	1,442
720.4 and 720.6 (amendments)	FDA 2512	109	7	763	.17	130
720.3, 720.6 (notices of discontinuance)	FDA 2512	55	41	2,255	.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.

Dated: December 9, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29685 Filed 12–15–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0629]

Draft Guidance for Industry on Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches.'' This draft guidance is intended to inform pharmaceutical manufacturers of the agency's thinking regarding genotoxic and carcinogenic impurities in drug substances and drug products, including biologic products that are regulated by the Center for Drug Evaluation and Research (CDER), and to provide recommendations on how to evaluate the safety of these impurities during clinical development and for marketing applications. This draft guidance, when finalized, will clarify FDA's additional testing and exposure threshold recommendations for situations in which genotoxic or carcinogenic impurities are present. This draft guidance addresses synthetic impurities and degradants in drug substances, but does not otherwise address the genotoxicity or carcinogenicity of actual drug substances or intended drug product ingredients. This draft guidance also applies to known starting materials or anticipated reaction products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by February 17, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: David Jacobson-Kram, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6488, Silver Spring, MD 20993–0002, 301–796–0175.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches.'' This draft guidance is intended to inform pharmaceutical manufacturers of the agency's thinking regarding genotoxic and carcinogenic impurities in drug substances and drug products, including biologic products regulated by CDER,