

available to a person with such a disease or condition unless an exemption is granted, because there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose the disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury with the probable benefit to health from using the device outweighing the risk of injury or illness from its use. This takes into account the probable risks and

benefits of currently available devices or alternative forms of treatment.

The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) exempt a HUD from the effectiveness requirements under sections 514 and 515 of the act, provided that the device meets requirements set forth under section 520(m) of the act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from

making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of a HUD is in compliance with the HUD provisions under section 520(m) of the act.

In the **Federal Register** of October 1, 2008 (73 FR 57108), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
814.102	14	1	14	40	560
814.104	6	1	6	320	1,920
814.106	6	2	12	50	600
814.108	32	1	32	80	2,560
814.116(e)(3)	1	1	1	1	1
814.124(a)	5	1	5	1	5
814.124(b)	4	1	4	2	8
814.126(b)(1)	45	1	45	120	5,400
Total					11,054

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Hours
814.126(b)(2)	45	1	45	2	90
Total					90

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

The number of respondents in tables 1 and 2 of this document are an average from data for the previous 3 years, i.e., fiscal year 2005–2007. The number of annual reports submitted under § 814.126(b)(1) in table 1 reflects an increase to 45 respondents with approved HUD applications. Likewise, under § 814.126(b)(2) in table 2, the number of recordkeepers increased to 45.

Dated: December 9, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29672 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–0633]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Adverse Drug Experience Reporting

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 postmarketing adverse drug experience reporting and recordkeeping requirements.

DATES: Submit written or electronic comments on the collection of information by February 17, 2009.

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:

Elizabeth Berbakos, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3792.

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.

Postmarketing Adverse Drug Experience Reporting—21 CFR 310.305 and 314.80 (OMB Control Number 0910-0230)—Extension

Sections 201, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 352, 355, and 371) require that marketed drugs be safe and effective. In order to know whether drugs that are not safe and effective are on the market, FDA must be promptly informed of adverse experiences occasioned by the use of marketed drugs. In order to help ensure this, FDA issued regulations at §§ 310.305 and 314.80 (21 CFR 310.305 and 314.80) to impose reporting and recordkeeping requirements on the drug industry that would enable FDA to take the action necessary to protect the public health from adverse drug experiences.

All applicants who have received marketing approval of drug products are required to report to FDA serious, unexpected adverse drug experiences, as well as followup reports when needed (§ 314.80(c)(1)). This includes reports of all foreign or domestic adverse experiences as well as those based on information from applicable scientific literature and certain reports from postmarketing studies. Section 314.80(c)(1)(iii) pertains to such reports submitted by non-applicants. Under § 314.80(c)(2), applicants must provide periodic reports of adverse drug experiences. A periodic report includes, for the reporting interval, reports of serious, expected adverse drug experiences and all nonserious adverse drug experiences and an index of these reports, a narrative summary and analysis of adverse drug experiences and a history of actions taken because of adverse drug experiences. Under § 314.80(i), applicants must keep records of all adverse drug experience

reports known to the applicant for 10 years.

For marketed prescription drug products without approved new drug applications or abbreviated new drug applications, manufacturers, packers, and distributors are required to report to FDA serious, unexpected adverse drug experiences as well as followup reports when needed (§ 310.305(c)). Section 310.305(c)(5) pertains to the submission of followup reports to reports forwarded by FDA. Under § 310.305(f), each manufacturer, packer, and distributor shall maintain for 10 years records of all adverse drug experiences required to be reported.

The primary purpose of FDA's adverse drug experience reporting system is to provide a signal for potentially serious safety problems with marketed drugs. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the marketed drug provide the opportunity to collect information on rare, latent, and long-term effects. Signals are obtained from a variety of sources, including reports from patients, treating physicians, foreign regulatory agencies, and clinical investigators. Information derived from the adverse drug experience reporting system contributes directly to increased public health protection because the information enables FDA to make important changes to the product's labeling (such as adding a new warning), decisions about risk evaluation and mitigation strategies or the need for postmarket studies or clinical trials, and when necessary, to initiate removal of a drug from the market.

Respondents to this collection of information are manufacturers, packers, distributors, and applicants. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
310.305(c)(5)	1	1	1	1	1
314.80(c)(1)(iii)	5	1	5	1	5
314.80(c)(2)	642	17.88	11,478	60	688,680
Total					688,686

¹ The reporting burden for §§ 310.305(c)(1), (c)(2), and (c)(3), and 314.80(c)(1)(i) and (c)(1)(ii) was reported under OMB No. 0910-0291. The capital costs or operating and maintenance costs associated with this collection of information are approximately \$25,000 annually.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

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

¹There 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

oir_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