DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0217]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Cosmetic Product Voluntary Reporting 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 November 10, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Cosmetic Product Voluntary Reporting Program—21 CFR Part 720 (OMB Control Number 0910–0030)—Extension

Under the Federal Food, Drug, and Cosmetic Act (the act), 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), cannot legally be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, FDA requests under part 720 (21 CFR part 720), but does not require, 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 places cosmetic product filing information in a computer database 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 has developed an electronic submission system for filing Forms FDA 2512, FDA 2512a, and FDA 2514 that will reduce the reporting burden for respondents and FDA. The system is currently undergoing additional beta testing and implementation is anticipated for fall 2005.

In the **Federal Register** of June 13, 2005 (70 FR 34142), FDA published a 60-day notice requesting public comment on the proposed extension of an existing collection of information described by the regulations in part 720. FDA received two letters, one from a trade association and one from a cosmetic company, each containing one or more comments, in response to the proposed extension of existing collection of information for part 720.

The trade association commended the agency for making the Cosmetic Product Voluntary Reporting Program less burdensome on the cosmetic industry by modernizing the program to take advantage of technological advances. The cosmetic company stated, however, that the requirement for both the ingredient name and a 9-digit identification number on Form FDA 2512a is burdensome.

FDA appreciates the trade association's remarks as well its assistance in making the voluntary reporting system more efficient. As to the burdensomeness of the dual requirement expressed by the cosmetic company, FDA expects to have its new system for electronic submission of cosmetic ingredient information to the Cosmetic Product Voluntary Reporting Program, which is currently in the beta testing stage, implemented in fall 2005. FDA expects that the new system will greatly simplify the submission of cosmetic ingredient information to the program by, among other things, permitting either the identification number or ingredient name to be submitted (except for new ingredients).

The cosmetic company also requested that FDA accept submission of a single Form FDA 2512 for groups of hair color preparations for which only the amounts of color additive ingredients are varied. FDA is not granting this request as it will be unnecessary once the agency implements its new electronic submission system. The agency's new electronic submission system will facilitate new submissions by making frequently used ingredients accessible from a ''favorites'' list and by making ingredient formulations previously submitted on the paper forms accessible to users of the new system upon proof of ownership.

The cosmetic company also requested that FDA modify the continuation footer in the paper version of Form FDA 2512a. FDA does not believe the requested change is necessary because the agency expects that its new electronic submission system will greatly reduce the use of paper versions of Forms FDA 2512, FDA 2512a, and FDA 2514.

The cosmetic company suggested that FDA revise the product categories in § 720.4(c) to include new types of products. FDA is not making the suggested revision. The agency does not believe this revision is necessary because each category already provides a subcategory for ''other preparations'' that covers products that do not fit in the specified subcategories.

Finally, the cosmetic company recommended that FDA's new electronic submission system provide for direct transfer of information from company databases to FDA's. FDA is not permitting this recommended direct transfer of information for security reasons. The agency has to limit the

ways people can enter data into the electronic submission system to protect the database from corruption.

FDA estimates the burden of the 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 and FDA 2512a	112	12.9	1,446	0.5	723
720.4 and 720.6 (amendments)	FDA 2512 and FDA 2512a	112	0.5	52	0.33	17
720.3 and 720.6 (notices of discontinuance)	FDA 2514	112	1	4	0.1	0.4
720.8 (requests for confidentiality)		1	1	1	1.5	1.5
Total						742

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

These estimates are based on FDA's experience with the Cosmetic Product Voluntary Reporting Program. The estimated annual total hours burden is 75 percent of the burden reported in 2002 due to decreased submissions. However, the number of respondents doubled, and FDA attributes this to increased interest in the program. FDA expects the number of submissions to increase accordingly in the next 3 years.

Dated: October 3, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20307 Filed 10–7–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0124]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 16, 2005 (70 FR 35097), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0374. The approval expires on September 30, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: October 3, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20308 Filed 10–7–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0401]

Draft Guidance for Industry and FDA Staff: Compliance With the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices.'' The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), as amended by the Medical Device User Fee Stabilization Act of 2005 (MDUFSA), requires that FDA issue guidance within 180 days of enactment (August 1, 2005) identifying the circumstances in which the name, abbreviation, or symbol identifying the manufacturer of an original device is not ''prominent and conspicuous.''

DATES: Submit written or electronic comments on this draft guidance so that they are received by close of business on November 10, 2005. FDA will not be able to consider comments received after that date in developing the final guidance. FDA may consider late comments at a future time if the