

Dated: June 25, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-16323 Filed 6-28-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0153]

Agency Information Collection Activities; Submission for OMB Review; 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 that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by July 30, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory

Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT:

Peggy Schlosburg, Office of Information Resources Management (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.

Voluntary Registration of Cosmetic Product Establishments—21 CFR Part 710 (OMB Control Number 0910-0027)—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) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, FDA requests that establishments that manufacture or package cosmetic products register with the agency on Form FDA 2511 entitled "Registration of Cosmetic Product Establishment." Regulations providing procedures for the voluntary registration of cosmetic product establishments are found in 21 CFR part 710.

Since mandatory registration of cosmetic establishments is not authorized by statute, voluntary registration provides FDA with the best information available about the location, business trade names used, and the type of activity (manufacturing or packaging) of cosmetic product establishments that participate in this program. In addition, the registration information is an essential part of planning onsite inspections to determine the scope and extent of noncompliance with applicable provisions of the act. The registration information is used to estimate the size of the cosmetic industry regulated. Registration is permanent, although FDA requests that firms submit an amended registration on Form FDA 2511 if any of the information originally submitted changes.

FDA uses registration information as input for a computer data base of cosmetic product establishments. This database is used for mailing lists to distribute regulatory information or to invite firms to participate in workshops on topics in which they may be interested.

In the **Federal Register** of April 13, 2001 (66 FR 19175), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Part	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
710	FDA 2511	50	1	50	0.4	20

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

The burden estimates are based on past experience and on discussions with registrants during routine communications. FDA receives an average of 50 registration submissions annually. There has been no change over the past 16 years in the number of submissions of Form FDA 2511 or in the time it takes to complete this form.

Dated: June 22, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0154]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Color Additive Certification Requests and Recordkeeping

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and

clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by July 30, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT:

Peggy Schlosburg, Office of Information Resources Management (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