Dated: June 25, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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

BILLING CODE 4160–01–S

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 BURDEN[1]

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.

[FR Doc. 01–16324 Filed 6–28–01; 8:45 am]

BILLING CODE 4160–01–S

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

has submitted the following proposed collection of information to OMB for review and clearance.

Color Additive Certification Requests and Recordkeeping—21 CFR Part 80—(OMB Control No. 0910–0216)—Extension

Section 721(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e(a)) provides that a color additive shall be deemed unsafe unless the color additive and its use are in conformity with a regulation that describes the conditions under which the color additive may be safely used, or unless the color additive and its use conform to the terms of an exemption for investigational use. If a regulation prescribing safe conditions of use has been issued, the color additive must be from a batch certified by FDA to conform to the requirements of that regulation and other applicable regulations, unless the color additive has been exempted from the certification requirement.

Section 721(c) of the act instructs the Secretary of Health and Human Services (the Secretary) (through FDA) to issue regulations providing for batch certification of color additives for which the Secretary finds such requirement to be necessary in the interest of protecting the public health. FDA's implementing regulations in part 80 (21 CFR part 80) specify the information that must accompany a request for certification of a batch of color additive and require certain records to be kept pending and after certification. FDA requires batch certification for all color additives listed in 21 CFR part 74 and for all color additives provisionally listed in 21 CFR part 82. Color additives listed in 21 CFR part 73 are exempt from certification.

Under § 80.21, a request for certification must include: Name of color additive, batch number and weight in pounds, name and address of manufacturer, storage conditions, statement of use(s), fee, and signature of requester. The request for certification must also include a sample of the batch of color additive that is the subject of the request. Under § 80.22, the sample must be labeled to show: Name of color additive, batch number and quantity, and name and address of the person requesting certification. A copy of the label or labeling to be used for the batch must accompany the sample. Under § 80.39, the person to whom a certificate is issued must keep complete records showing the disposal of all the color additive covered by the certificate. Such records are to be made available upon request to any accredited representative of FDA until at least 2 years after disposal of all of the color additive.

The request for certification of a batch of color additive is reviewed by FDA's Office of Cosmetics and Colors to verify that all of the required information has been included. Because the information required in the request for certification is unique to the specific batch of color additive involved, it must be generated for each batch. The information submitted with the request helps FDA to ensure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States. The batch number assigned by the manufacturer is a means of temporary identification until a certification lot number has been issued by FDA. After certification, the manufacturer's batch number helps ensure that the proper batch of color is indeed being used under the certification lot number issued by FDA. In the case of a batch that has been refused certification for noncompliance with the regulations, the manufacturer's batch number aids in tracing the ultimate disposal of that batch of color additive. The batch weight serves to account for the disposal of the entire batch. For example, it might be used in determining whether uncertified color has been sold under the lot number assigned to the batch by FDA or, in the event of a recall after certification, to determine whether all unused color has been recalled. In addition, the batch weight is the basis for assessing the certification fee. The name and address of the manufacturer of the color additive being submitted for certification allows FDA to contact the person responsible for its manufacture should a question arise concerning compliance with the regulations. Information on storage conditions pending certification is used to evaluate the possibility that the batch could have been inadvertently or intentionally altered in a manner that would make the sample submitted for certification analysis no longer representative of the batch. It is also used when an FDA investigator is sent to the site; the veracity of the storage statements is checked during normal plant inspections. Information on the uses is needed to ensure that all of the proposed uses are within the limits of the listing regulation for which the person seeking certification proposes that the color be certified. The statement of the fee on the certification request is for accounting purposes so that the person seeking certification can be promptly notified if any discrepancies appear. The information requested on the label of the sample submitted with the certification request is used to identify the sample. The regulations require an accompanying copy of the label or labeling to be used for the batch so that FDA can verify that the batch will be labeled appropriately when it enters commerce.

In the **Federal Register** of April 13, 2001 (66 FR 19174), 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 BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
80.21	41	106	4,346[2]	0.2	869
80.22	41	106	4,346[2]	0.05	217
Total					1,086

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

[2] Due to a clerical error, the total annual records that appeared in tables 1 and 2 in the FEDERAL REGISTER notice of April 13, 2001 (66 FR 19175), was incorrect. Tables 1 and 2 of this document contains the correct total.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
80.39	41	106	4,346[2]	0.25	1,086

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Due to a clerical error, the total annual records that appeared in tables 1 and 2 in the FEDERAL REGISTER notice of April 13, 2001 (66 FR 19175), was incorrect. Tables 1 and 2 of this document contains the correct total.

The estimated total annual burden for this information collection is 2,172 hours. Over the period fiscal year (FY) 1998 to 2000, FDA processed an average of 4,346 requests for certification of batches of color additives. Approximately 41 different respondents submitted requests for certification each year over the period FY 1998 to 2000. FDA obtained the estimates for the length of time necessary to prepare certification requests and accompanying samples and to comply with recordkeeping requirements from industry program area personnel.

Dated: June 22, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–16325 Filed 6–28–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1147–NC]

RIN 0938–AK51

Medicare Program; Update to the Prospective Payment System for Home Health Agencies for FY 2002

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice with comment period sets forth an update to the 60-day national episode rates and the national per-visit amounts under the Medicare prospective payment system for home health agencies.

DATES: *Effective Date:* The rate updates in this notice with comment period are effective on October 1, 2001.

Comment Period: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on August 28, 2001.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1147–NC, P.O. Box 8016, Baltimore, MD 21244–8016.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1147–NC. Comments received timely will be available for public inspection as they are received, generally beginning appropriately 3 weeks after publication of a document, in Room C5–12–08 of the headquarters Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD, on Monday through Friday of each week from 8:30 to 5 p.m. (phone: (410) 786–7197).

FOR FURTHER INFORMATION CONTACT:

Bob Wardwell (Project Manager), (410) 786–3254.

Susan Levy (Policy), (410) 786–9364.

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This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office.

I. Background; Recent Legislation on Payment to Home Health Agencies

A. Balanced Budget Act of 1997

The Balanced Budget Act of 1997 (BBA), Pub. L. 105–33, enacted on August 5, 1997, significantly changed the way Medicare pays for Medicare home health services. Until the implementation of a home health prospective payment system (HH PPS) on October 1, 2000, home health agencies (HHAs) received payment under a cost-based reimbursement system. Section 4603 of the BBA governed the development of HH PPS.

Section 4603(a) of the BBA provides the authority for the development of a PPS for all Medicare-covered home health services provided under a plan of care that were paid on a reasonable cost basis by adding section 1895, entitled ''Prospective Payment For Home Health Services,'' to the Social Security Act (the Act).

Section 1895(b)(1) of the Act requires the Secretary to establish a PPS for all costs of home health services paid under Medicare.

Section 1895(b)(2) of the Act requires the Secretary in defining a prospective payment amount to consider an appropriate unit of service and the number, type, and duration of visits furnished within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services.

Section 1895(b)(3)(A) of the Act requires that (1) the computation of a standard prospective payment amount include all costs of home health services covered and paid for on a reasonable cost basis and be initially based on the most recent audited cost report data available to the Secretary, and (2) the prospective payment amounts be standardized to eliminate the effects of case-mix and wage levels among HHAs.

Section 1895(b)(3)(C) of the Act requires the Secretary to reduce the prospective payment amounts if the