

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration 9509 '01 APR 11 AS

[Docket No. 01N-0154]

Agency Information Collection Activities; Proposed Collection; 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 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 the information collection provisions of FDA's regulations governing batch certification of color additives manufactured for use in foods, drugs, cosmetics, or medical devices in the United States.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (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: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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: (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.

Color Additive Certification Requests and Recordkeeping—(21 CFR Part 80)—(OMB Control Number 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.

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
80.21	41	106	4,344	0.2	869
80.22	41	106	4,344	0.05	217
Total				0.25	1,086

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
80.39	41	106	4,344	0.25	1,086
Total					1,086

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

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 4,344 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: 4/6/01
April 6, 2001.

oc0179

William K. Hubbard

William K. Hubbard,
Senior Associate Commissioner
for Policy, Planning, and Legislation.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

[Signature]

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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