testing sites; (11) assists NCID with the evaluation of new HIV-related tests; (12) conducts local and regional studies of HIV genotypic variations and antiretroviral drug resistance; (13) collaborates with NCID laboratories to develop a repository of stored sera and cells for studies of HIV and related infections.

Statistics and Data Management Branch (CK55). (1) Manages, directs, and coordinates the statistics and data management activities and services for the division and the Division of HIV/AIDS Prevention—Intervention Research and Support (DHAP/IRS); (2) provided leadership in the development of statistical and data management planning, policy, implementation, and evaluation; (3) provides data management and statistical support for HIV/AIDS surveillance, HIV serosuryveys, epidemiologic studies and other studies conducted within the division and DHAP/IRS; (4) creates mathematical models to project the incidence of AIDS and HIV infection; (5) develops, monitors, and evaluate projects to construct mathematical models of the spread of AIDS and HIV infection and other HIV and AIDS studies; (6) provides statistical models of epidemiologic parameters to describe the efficiency of HIV transmission and the incubation time for AIDS; (7) responds to inquiries from medical professionals, health departments, the media, and the public about AIDS epidemic statistical issues, including projections of the number of AIDS cases and estimates of person infected with HIV; (8) coordinates contracted programming services for the division.

Surveillance Branch (CK56). (1) Conducts surveillance of HIV infection and AIDS in coordination with State and local health departments to provide population-based data for public health policy development and evaluation; (2) maintains, analyzes, and disseminates information from the national confidential registry of HIV/AIDS cases; (3) monitors HIV-related morbidity and mortality and the use of recommendations for prevention and treatment of HIV infection and AIDS; (4) promotes uses of surveillance data for prevention and evaluation; (5) conducts surveillance of special populations of epidemiologic importance, e.g., persons with HIV–2 infection, health care workers for occupationally related HIV transmission, and person reported with unrecognized modes of transmission; (6) in coordination with State and local health departments, conducts population-based surveillance of HIV-related risk behaviors; (7) assesses socioeconomic, educational, and other factors of use in targeting and evaluating prevention and care programs; (8) evaluates surveillance systems for HIV infection and AIDS and modifies surveillance methodologies as needed to meet changing needs of HIV/AIDS programs; (9) manages extramural funding of surveillance activities and provides consultations and technical assistance on surveillance activities and methodologies to State and local health departments and national and international organizations and agencies.

Dated: August 24, 1998.

Stephen B. Thacker,

Acting Deputy Director, Centers for Disease Control and Prevention.

[FR Doc. 98–23476 Filed 8–31–98; 8:45am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0378]

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 (the PRA).

DATES: Submit written comments on the collection of information by October 1, 1998.

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: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. 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 section 3507 of the PRA (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 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 additive and its use are in conformity with a regulation that describes the conditions under which the additive may be safely used, or unless the 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 additive must be from a batch certified by FDA to conform to the requirements of that regulation and other applicable regulations, unless the additive has been exempted from the certification requirement.

Section 721(c) of the act instructs the Secretary of Health and Human Services (through FDA) to issue regulations providing for batch certification of color additives for which she finds such requirement to be necessary in the interest of protecting the public health. FDA's implementing regulations in 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 requestor. 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 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. Since 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 disposition of that batch of color additive. The batch weight serves to account for the disposition 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 BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
80.21	20	152	4,091	0.2	818
80.22	20	152	4,091	0.05	205
Total					1,023

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

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	27	152	4,091	0.25	1,023
Total					1,023

[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 2,046 hours. Over the period fiscal year (FY) 1995 to FY 1997, FDA processed an average of 4,091 requests for certification of batches of color additives. Approximately 20 different respondents submitted requests for certification each year over the period FY 1995 to FY 1997. The estimates for the length of time necessary to prepare certification requests and accompanying samples, and to comply with recordkeeping requirements were obtained from industry program area personnel.

Dated: August 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–23401 Filed 8–31–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0336]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Premarket Notification Submission 510(k), Subpart E

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 (the PRA).

DATES: Submit written comments on the collection of information by October 1, 1998.

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: Desk Officer for FDA.