TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total
226.42	115	260	29,000	0.75	22,425
226.58	115	260	29,000	1.75	52,325
226.80	115	260	29,000	0.75	22,425
226.102	115	260	24,000	1.75	52,325
226.110	115	260	29,000	0.25	7,475
226.115	115	10	1,150	0.5	575
Total					157,550

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

The estimate of the time required for record preparation and maintenance is based on agency communications with industry. Other information needed to calculate the total burden hours (i.e., manufacturing sites, number of Type A medicated articles being manufactured, etc.) are derived from agency records and experience.

Dated: November 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–23351 Filed 11–30–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0279]

Agency Information Collection Activities; Submission for Office of Management and Budget 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 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 January 2, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0216. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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—OMB Control Number 0910–0216)—Extension

FDA has regulatory oversight for color additives used in foods, drugs, cosmetics, and medical devices. 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 to be unsafe unless it meets the requirements of a listing regulation, including any requirement for batch certification, and is used in accordance with the regulation. FDA lists color additives that have been shown to be safe for their intended uses in title 21 of the Code of Federal Regulations (CFR). 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 exempted from certification.

The requirements for color additive certification are described in part 80 (21 CFR part 80). In the certification procedure, a representative sample of a new batch of color additive, accompanied by a ''request for certification'' that provides information about the batch, must be submitted to FDA's Office of Cosmetics and Colors. FDA personnel perform chemical and other analyses of the representative sample and, providing the sample satisfies all certification requirements, issue a certification lot number for the batch. FDA charges a fee for certification based on the batch weight and requires manufacturers to keep records of the batch pending and after certification.

Under § 80.21, a request for certification must include: Name of color additive, manufacturer's batch number and weight in pounds, name and address of manufacturer, storage conditions, statement of use(s), certification fee, and signature of person requesting certification. Under § 80.22, a request for certification must include a sample of the batch of color additive that is the subject of the request. The sample must be labeled to show: Name of color additive, manufacturer's batch number and quantity, and name and address of person requesting certification. 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 purpose for collecting this information is to help FDA assure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States. The required information is unique to the batch of color additive that is the subject of a request for certification. The manufacturer's batch number is used for temporarily identifying a batch of color additive until FDA issues a certification lot number and for identifying a certified batch during inspections. The manufacturer's batch number also aids

in tracing the disposal of a certified batch or a batch that has been refused certification for noncompliance with the color additive regulations. The manufacturer's batch weight is used for assessing the certification fee. The batch weight also is used to account for the disposal of a batch of certified or certification-rejected color additive. The batch weight can be used in a recall to determine whether all unused color additive in the batch has been recalled. The manufacturer's name and address and the name and address of the person requesting certification are used to contact the person responsible should a question arise concerning compliance with the color additive regulations. Information on storage conditions pending certification is used to evaluate whether a batch of certified color additive is inadvertently or intentionally altered in a manner that would make the sample submitted for certification analysis unrepresentative of the batch. FDA checks storage information during inspections. Information on intended uses for a batch of color additive is used to assure that a batch of certified color additive will be used in accordance with the requirements of its listing regulation. The statement of the fee on a certification request is used for accounting purposes so that a person requesting certification can be notified promptly of any discrepancies.

In the **Federal Register** of July 24, 2007 (72 FR 40310), FDA published a 60-day notice requesting public comment on the information collection provisions. 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	32	174	5,568	0.20	1,114
80.22	32	174	5,568	0.05	278
Total				0.25	1,392

[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 of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
80.39	32	174	5,568	0.25	1,392
TOTAL					1,392

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

FDA bases its estimate on its review of the certification requests received over the past 3 fiscal years (FY). The annual burden estimate for this information collection is 2,784 hours. The estimated reporting burden for this information collection is 1,392 hours and the estimated recordkeeping burden for this information collection is 1,392 hours. From FY 2004 to FY 2006, FDA processed an average of 5,568 responses (requests for certification of batches of color additives) per year. There were 32 different respondents, corresponding to an average of approximately 174 responses from each respondent per year. Using information from industry personnel, FDA estimates that an average of 0.25 hour per response is required for reporting (preparing certification requests and accompanying sample labels) and an average of 0.25 hour per response is required for recordkeeping.

On February 13, 2006, FDA introduced a Web-based Color Certification information system. The system was fully operational for FY 2007. This system allows certifiers to request color certification on-line, follow their submissions through the process, and obtain information on account status. The system sends back the certification results electronically, allowing certifiers to sell their certified color before receiving hard copy certificates. Any delays in the system result only from shipment of color additive samples to FDA's Office of Cosmetics and Colors for analysis. FDA expects future reductions in the hour burdens for reporting and recordkeeping from use of the Web-based system.

Dated: November 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–23352 Filed 11–30–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007F–0454]

General Mills, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that General Mills, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ultraviolet radiation for the reduction of pathogens and other microorganisms in aqueous sugar solutions and potable water intended for use in food production.

FOR FURTHER INFORMATION CONTACT: Laura A. Dye, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1275.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7M4770) has been filed by General Mills, Inc., One General Mills Blvd., Minneapolis, MN 55426. The petition proposes to amend the food additive regulations in § 179.39 *Ultraviolet radiation for the processing and treatment of food* (21 CFR 170.39) to provide for the safe use of ultraviolet radiation for the reduction of pathogens