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.

**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.

### Premarket Notification Submission 510(k), Subpart E—(OMB Control Number 0910–0120—Reinstatement)

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) and the implementing regulation, 21 CFR 807.81, require a person/manufacturer who intends to market a medical device to submit a premarket notification submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use.

Section 510(k) of the act allows for exemptions to the 510(k) submissions, i.e., a premarket notification submission would not be required if FDA determines that premarket notification is not necessary for the protection of the public health, and they are specifically exempted through the regulatory process. Under 21 CFR 807.85, ''Exemption from premarket notification,'' a device is exempt from premarket notification if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution. In addition, the device must meet one of the following conditions: (1) It is intended for use by a patient named in order of the physician or dentist (or other specially qualified persons), or (2) it is intended solely for use by a physician or dentist and is not generally available to other physicians or dentists.

A commercial distributor who places a device into commercial distribution for the first time under their own name and a repackager who places their own name on a device and does not change any other labeling or otherwise affect the device, shall be exempted from premarket notification if the device was legally in commercial distribution before May 28, 1976, or a premarket notification was submitted by another person.

The information collected in a premarket notification is used by the medical, scientific, and engineering staffs of FDA in making determinations as to whether or not devices can be allowed to enter the U.S. market. The premarket notification review process allows for scientific and/or medical review of devices, subject to section 510(k) of the act, to confirm that the new devices are as safe and as effective as legally marketed predicate devices. This review process, therefore, prevents potentially unsafe and/or ineffective devices, including those with fraudulent claims, from entering the U.S. market. This information will allow FDA to collect data to ensure that the use of the device will not present an unreasonable risk for the subject and will not violate the subject's rights. The respondents to this information collection will primarily be medical device manufacturers and businesses.

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 |
|---|---|---|---|---|---|
| 807.81 and 807.87 | 5,000 | 1 | 5,000 | 80 | 400,000 |

[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 |
|---|---|---|---|---|---|
| 807.93 | 2,000 | 10 | 20,000 | 0.5 | 10,000 |

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

FDA has based these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in Tables 1 and 2 of this document. Based on the trend in the past 3 years, an estimated 5,000 submissions are expected each year. FDA's administrative and technical staff, who are familiar with the requirements for submission of premarket notifications, estimate that an average of 80 hours are required to prepare a submission (exclusive of preparing clinical data, research, etc.). FDA, therefore, estimates that a total of 400,000 hours of effort is required for the 5,000 submissions. It is also estimated that the respondents will receive requests for an average of 20,000 documents. At an estimated one-half hour to process these documents, an additional 10,000 recordkeeping hours are expected for this program.

Dated: August 24, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98–23402 Filed 8–31–98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98N–0357]**

### Agency Information Collection Activities; Announcement of OMB Approval; Medical Devices; Current Good Manufacturing Practice (CGMP) Quality System (QS)

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing