Dated: June 30, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy Coordination.*

[FR Doc. 99–17332 Filed 7–7–99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 99N–0670]**

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Labeling Requirements for Color Additives (Other Than Hair Dyes) and Petitions

**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 August 9, 1999.

**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 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.

#### Labeling Requirements for Color Additives (Other Than Hair Dyes)—21 CFR 70.25 and Petitions—21 CFR 71.1 (OMB Control Number 0910-0185—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 to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or unless the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the act. Color additive petitions are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 (21 CFR 71.1) specifies the information that a petitioner must submit in order to establish the safety of a color additive and to secure the issuance of a regulation permitting its use.

FDA's scientific personnel review color additive petitions to ensure that the intended use of the color additive in or on food, drugs, cosmetics, and medical devices is suitable and safe. Color additive petitions were specifically provided for by Congress when it enacted the Color Additive Amendments of 1960 (Pub. L. 94–295). If FDA stopped accepting color additive petitions or stopped requiring them to contain the information specified in § 71.1, the number of new color additives approved would decrease.

FDA's color additive labeling requirements in § 70.25 (21 CFR 70.25) require that color additives that are to be used in food, drugs, devices, or cosmetics be labeled with sufficient information to ensure their safe use.

*Description of Respondents:* Business or other for profit.

In the **Federal Register** of April 12, 1999 (64 FR 17672), the agency requested comments on the proposed collections 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 | Total Operating & Maintenance Costs |
|---|---|---|---|---|---|---|
| 70.25 | 5 | 1 | 5 | | | |
| 71.1 | 5 | 1 | 5 | 1,866 | 9,330 | $14,200 |
| Total | | | | | 9,330 | |

[1] There are no capital costs associated with this collection of information.

This estimate is based on the average number of new color additive petitions received in 1997 and 1998. Although the burden varies with the type of petition submitted, a color additive petition involves analytical work and appropriate toxicology studies, as well as the work of drafting the petition itself. Because labeling requirements under § 70.25 for a particular color additive involve information required as part of the color additive petition safety review process, the estimate for the number of respondents is the same for § 70.25 as for § 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Color additives are subjected to payment of fees for the petitioning process. The listing fee for a color additive petition ranges from $1,600 to $3,000, depending on the intended use of the color and the scope of the requested amendment. A complete schedule of fees is set forth in 21 CFR 70.19. An average of two Category A and three Category B color additive petitions are expected per year. The maximum color additive petition fee for a Category A petition is $2,600 and the maximum color additive petition fee for a Category B petition is $3,000. Because an average of five color additive petitions are expected per calendar year, the estimated total annual cost burden to petitioners for this startup cost would be less than or equal to $14,200 (2 x $2,600 + x $3,000 listing fees = $14,200).

Dated: June 30, 1999.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning and Legislation.*

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