

committees that make recommendations regarding messaging and other stakeholders with information about the projected costs to vendors and laboratories and about the time frames required for and the barriers to implementation.

CDC will use the survey to gauge the technological readiness and the cost factors affecting secure electronic transmission of infectious disease data to government agencies. These transmissions will act as part of an early warning system leading to more timely

response to infectious disease outbreaks. This survey responds to President Clinton's request for the increased use of modern technology to identify and prevent outbreaks of food-borne illness. The total annual burden hours are 121.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hrs.)
Contact Information Form .....	56	1	0.1667
Mail Survey .....	56	2	0.50
Telephone Follow-up .....	56	2	0.50

**Nancy Cheal,**

*Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 99-17273 Filed 7-7-99; 8:45 am]

BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Revised Vessel Sanitation Operations Manual; Public Meeting**

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting.

*Name:* Discussion of the second draft of the revised Vessel Sanitation Operations Manual—Public meeting between CDC and the cruise ship industry, private sanitation consultants, and other interested parties.

*Time and Date:* 9 a.m.–4:30 p.m., October 5, 1999; 9 a.m.–4:30 p.m., October 6, 1999; 9 a.m.–12 noon, October 7, 1999.

*Place:* Auditorium, Port Everglades Administration Building, 1850 Eller Drive, Fort Lauderdale, Florida 33316.

*Status:* Open to the public, limited by the space available. The meeting room accommodates approximately 100 people.

*Purpose:* CDC announced its intention to revise the *Vessel Sanitation Operations Manual* in the **Federal Register** of July 9, 1998 (Volume 63, Number 131). Input and comments from the public were requested of and received from the cruise ship industry, private sanitation consultants, and other interested parties, and were discussed in detail at a public meeting held in Fort Lauderdale on April 14–16, 1999. On the basis of comments received, VSP staff have written a second draft of the revised manual and will discuss the revisions at this public meeting.

*Matters To Be Discussed:* Agenda items will include a thorough discussion of each section of the second draft of the revised operations manual. A copy of the second draft will be available for review by August 6, 1999. To obtain a copy, contact the VSP

in Atlanta at the address or phone number below, or go to the VSP Home Page on the Internet at <http://www.cdc.gov/nceh/programs/vsp>.

For a period of 15 days following the meeting, through October 22, 1999, the official record of the meeting will remain open so that additional materials or comments may be submitted to be made part of the record of the meeting. VSP staff will then finalize the revised operations manual and publish the final in the **Federal Register**.

Advanced registration for this important meeting is encouraged. If you plan to attend, please provide your name, title, company name, mailing address, telephone number, facsimile number, and E-mail address to Dorothy Johnson, Management Assistant, facsimile 770/488-4127 or E-mail: [dgj0@cdc.gov](mailto:dgj0@cdc.gov).

*Contact Person for More Information:* David Forney, Acting Chief, VSP, telephone 770/488-7333 or E-mail: [dfl1@cdc.gov](mailto:dfl1@cdc.gov); or Daniel Harper, Senior Environmental Health Officer, VSP, telephone 770/488-3524, E-mail: [dmh2@cdc.gov](mailto:dmh2@cdc.gov); or write to us at Vessel Sanitation Program, CDC, 4770 Buford Highway, NE, M/S F-16, Atlanta, Georgia 30341-3724.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 30, 1999.

**Carolyn J. Russell,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 98N-1110]

**Agency Information Collection Activities; Announcement of OMB Approval; Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "CGMP Regulations for Finished Pharmaceuticals" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of April 19, 1999 (64 FR 19180), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0139. The approval expires on June 30, 2002. A copy of the supporting statement for this information collection is available on the Internet at "<http://www.fda.gov/ohrms/dockets>".

Dated: June 30, 1999.

**Margaret M. Dotzel,**  
Acting Associate Commissioner for Policy  
Coordination.

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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<sup>1</sup>

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	

<sup>1</sup> 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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