Dated: May 13, 1998.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

Appendix A

Sample

Fax to: Henry Falk, M.D., Director, Division of Environmental Hazards and Health Effects, National Center for Environmental Health Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop F–28, Atlanta, GA 30341–3724, Facsimile (770) 488–4127

Fax copy to: Chief, Vessel Sanitation Program, National Center for Environmental Health Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop F–16, Atlanta, GA 30341–3724, Facsimile (770) 488–4127

We request the presence of a PHS representative for shipyard consultation on cruise liner (NAME). We tentatively expect to take delivery of the cruise liner on (DATE). We would like to schedule the shipyard consultation for (DATE). We expect the consultation to take approximately (NUMBER OF DAYS).

We will pay CDC in accordance with the inspection fee published in the **Federal Register**, and for all expenses in connection with the shipyard inspection. We will make all necessary arrangements for lodging and transportation, which includes airfare and ground transportation in (CITY, STATE, COUNTRY). We will provide in-kind for lodging and transportation expenses. All remaining expenses, such as en route per diem and meals and miscellaneous expenses, including ground transportation to and from the airport nearest the representatives work site or residence, should be sent to the following address:

Company
Attention:
Street Address
City, State, Country
Zip Code
Office Telephone Number
Facsimile Number

If you have questions regarding this confirmation, please contact:

Signed:

[FR Doc. 98–13212 Filed 5–18–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0194]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's regulations governing batch certification of color additives manufactured for use in foods, drugs, cosmetics or medical devices in the United States.

DATES: Submit written comments on the collection of information by July 20, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Color Additive Certification Requests and Recordkeeping—21 CFR Part 80 (OMB Control Number 0910–0216—Extension)

Section 721(a) of the Federal Food, and 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 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 part 80 (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/address of manufacturer, storage conditions, statement of use(s), fee, and signature of requester. 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 assure 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 which the person seeking certification proposes that the color be certified for it is to assure that all of the proposed uses are within the limits of the listing regulation. 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 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	.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 additive. 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: May 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13228 Filed 5–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Open Meeting for Representatives of Health Professional Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting with representatives of health professional organizations. The meeting will be chaired by Sharon Smith Holston, Deputy Commissioner for External Affairs. The agenda will include presentations and discussions on the main topic of emerging infectious diseases. FDA staff will make presentations on FDA's involvement in the President's Food Safety Initiative, antimicrobial resistance, and issues in vaccine development and diagnostics. There will also be brief updates on