

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

No. of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Response	Total Hours
12	1	12	8	96

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of January 28, 2002 (67 FR 3902), the agency requested comments on the proposed collections of information. No comments were received.

Dated: June 6, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02N-0054]

#### 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.

**DATES:** Submit written comments on the collection of information by July 15, 2002.

**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: Stuart Shapiro, 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 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 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 (Public Law 94-295). If FDA stopped accepting color additive petitions or stopped requiring them to contain the information specified in § 71.1, there would be no way to bring new uses of listed color additives or new color additives to market. 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.

Respondents are businesses engaged in the manufacture or sale of color additives for use in food, drugs, cosmetics, or medical devices.

In the **Federal Register** of February 28, 2002 (67 FR 9297), the agency requested comments on the proposed collection of information. No comments were received that pertained to this collection of information.

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 Operating and Maintenance Costs	Total Hours
70.25	0	1	0	0	0	0
71.1	3	1	3	2,000	\$8,600	6,000
Total						6,000

<sup>1</sup> There are no capital costs associated with this collection of information.

This estimate is based on the number of new color additive petitions received in fiscal year 2000 and the total hours expended by petitioners to prepare the petitions. 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 one category A and two 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. Since an average of three color additive petitions are expected per calendar year, the estimated total annual cost burden to petitioners for this start-up cost would be less than or equal to \$8,600.

Dated: May 23, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01D-0435]

#### International Conference on Harmonisation; Draft Guidance on Electronic Common Technical Document Specification; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a second draft guidance entitled "Electronic Common Technical Document Specification" (eCTD). The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance defines the means for industry-to-agency transfer of regulatory information that will facilitate the creation, review, life cycle management, and archiving of the electronic submission. The draft guidance is intended to assist industry in transferring electronically their marketing applications for human drug and biological products to a regulatory authority.

**DATES:** Submit written or electronic comments on the draft guidance by August 1, 2002. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the

Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3844, FAX 888-CBERFAX. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

#### FOR FURTHER INFORMATION CONTACT:

*Regarding the draft guidance:* Robert Yetter, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373, or Gregory V. Brolund, Center for Drug Evaluation and Research (HFD-70), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3517.

*Regarding the ICH:* Janet J. Showalter, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0864.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical

requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedure for publishing ICH guidances. As of April 2000, we no longer include the text of ICH guidances in the **Federal Register**. Instead, we publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance will be placed in the docket and can be obtained through regular agency sources (see **ADDRESSES**). Draft guidances are left in the original ICH format. The final guidance is reformatted to conform to the GGP style before publication.

In June 2001, the ICH Steering Committee agreed that a draft guidance entitled "Electronic Common Technical Document Specification" would be made available for public comment and testing. The draft guidance, a product of the Multidisciplinary Group 2 (M2) Expert Working Group (EWG) of the ICH, was made available for comment in the **Federal Register** of November 28, 2001 (66 FR 59431). Comments about the draft guidance were considered by FDA and the M2 EWG, and in February 2002, the ICH Steering Committee agreed that a second draft guidance should be made available for public comment (step 2).

The draft guidance on the eCTD provides guidance on industry-to-agency electronic transfer of marketing applications for human drug and