

Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: March 25, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98-8296 Filed 3-30-98; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: ACF-196 Temporary Assistance for Needy Families Financial Reporting Form.

OMB No.: 0970-0165.

Description: The form provides specific data regarding claims and

provides a mechanism for States to request grant awards and certify the availability of State matching funds. Failure to collect this data would seriously compromise ACF's ability to monitor expenditures. This information is also used to estimate outlays and may be used to prepare ACF budget submissions to Congress. The following citations should be noted in regards to this collection: 405(c)(1); 409(a)(7); and 4-09(a)(1).

Respondents: State Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF-196	54	4	8	1,728

Estimated Total Annual Burden Hours: 1,728.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: March 25, 1998.

Robert Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98-8299 Filed 3-30-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95C-0211]

Wesley Jessen Corp.; Withdrawal of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a color additive petition (CAP 5C0246) proposing that the color additive regulations be amended to provide for the safe use of 2-[[2,5-diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol to tint soft (hydrophilic) contact lenses.

FOR FURTHER INFORMATION CONTACT: John R. Bryce, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3023.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 18, 1995 (60 FR 43157), FDA announced that a color additive petition (CAP 5C0246) had been filed by Pilkington Barnes Hind. The petition proposed to amend the color additive regulations in § 73.3115 2-[[2,5-Diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol (21 CFR 73.3115) to provide for the safe use of the color additive to tint soft (hydrophilic) contact lenses. Since the publication of the filing notice, Pilkington Barnes Hind has been acquired by Wesley Jessen Corp., 333 East Howard Ave., Des Plaines, IL 60018-5903. Wesley Jessen Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 71.6(c)(2)).

Dated: March 9, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98-8303 Filed 3-30-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F-0183]

Ciba Specialty Chemicals Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba Specialty Chemicals Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 2-hydroxy-1-[4-(2-hydroxyethoxy)phenyl]-2-methyl-1-propanone as a photoinitiator for adhesives and pressure-sensitive adhesives intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4589) has been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., Tarrytown, NY

10591–9005. The petition proposes to amend the food additive regulations to provide for the safe use of 2-hydroxy-1-[4-(2-hydroxyethoxy)phenyl]-2-methyl-1-propanone as a photoinitiator for adhesives complying with § 175.105 *Adhesives* (21 CFR 175.105) and pressure-sensitive adhesives complying with § 175.125 *Pressure-sensitive adhesives* (21 CFR 175.125) intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: March 13, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–8302 Filed 3–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0172]

Amended Procedures for Advisory Panel Meetings; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled “Amended Procedures for Advisory Panel Meetings.” The purpose of the guidance document is to establish standard operating procedures to be followed by the Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), FDA personnel, and interested persons outside FDA in carrying out the Federal Food, Drug, and Cosmetic Act (the act), as amended through the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Written comments concerning the draft guidance must be received by June 29, 1998. After the close of the comment period, written comments may be submitted at any time to the contact person listed below.

ADDRESSES: Written comments concerning the draft guidance that are submitted within the 90 days comment period must be addressed to the Dockets

Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in heading of this document. Submit written requests for singles copies of the draft guidance to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

Nancy J. Pluhowski, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022.

SUPPLEMENTARY INFORMATION:

I. Background

The guidance document entitled “Amended Procedures for Advisory Panel Meetings” was developed to establish standard operating procedures to be followed by the CDRH, CBER, FDA personnel, and interested persons outside FDA in carrying out section 513(b)(6) of the act (21 U.S.C. 360c(b)(6)) as amended by section 208 of FDAMA. Beginning on February 19, 1998, section 513(b)(6)(A) of the act requires that FDA provide to any person whose device is subject to a classification panel review be given the same access to data and information submitted to a classification panel except data and information that are not available for public disclosure under the Freedom of Information Act (5 U.S.C. 552). FDAMA further amended the act to require any person whose device is under review by a classification panel to have the opportunity to submit information based on the data or information provided in the application to the panel for its review. It also provides the same opportunity as the Secretary of Health and Human Services to participate in panel meetings. Section 513(b)(6)(B) of the act requires that adequate time be provided for initial presentations and for response to any differing views by persons whose devices are specifically the subject of a classification panel, and that free and open participation by all interested persons be encouraged.

II. Significance of Guidance

The guidance document represents the agency’s current thinking on the amended procedures for advisory panel meetings. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

The guidance document entitled “Amended Procedures for Advisory Panel Meetings” is a Level 1 guidance document under FDA’s Good Guidance Practices Policy. Public comment prior to implementation of the guidance document is not required because the guidance is needed to implement new statutory requirements enacted by FDAMA.

III. Comments

Interested persons may, on or before June 29, 1998, submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. After June 29, 1998, written comments may be submitted at any time to the contact person listed above.

IV. Electronic Access

In order to receive the draft guidance entitled “Amended Procedures for Advisory Panel Meetings” via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 413, followed by the pound sign (#). Then follow the remaining voice prompt to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes the guidance document entitled “Amended Procedures for Advisory Panel Meetings,” device safety alerts, **Federal Register** reprints, information on premarket submissions