

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention (CDC)**

**Advisory Committee for Injury Prevention and Control (ACIPC): Family and Intimate Violence Prevention Subcommittee Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following subcommittee meeting.

*Name:* ACIPC Family and Intimate Violence Prevention Subcommittee.

*Time and Date:* 8:30 a.m.–4:30 p.m., November 16, 1999.

*Place:* Holiday Inn Select-Atlanta Decatur Hotel and Conference Plaza, 130 Clairemont Avenue, Decatur, Georgia 30033.

*Status:* Open to the public, limited only by the space available.

*Purpose:* To provide and make recommendations to ACIPC and the Director, National Center for Injury Prevention and Control (NCIPC), regarding feasible goals for prevention and control of family and intimate violence sexual assault. The Subcommittee will make recommendations regarding policies, strategies, objectives and priorities.

*Matters to be Discussed:* The Subcommittee will discuss and provide recommendations to the CDC on future directions for program activities, evaluation, and research related to the National Resource Council Report, Understanding Violence Against Women.

Agenda items are subject to change as priorities dictate.

*Contact Person for more Information:* Lemyra DeBruyn, Ph.D., Acting Team Leader, Family and Intimate Violence Prevention Team, Division of Violence Prevention, NCIPC, CDC, 4770 Buford Highway, NE, M/S K60, Atlanta, Georgia 30341, telephone 770/488-4410.

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: October 22, 1999.

**Carolyn J. Russell,**

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

[FR Doc. 99-28137 Filed 10-27-99; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99N-2549]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Cosmetic Product Voluntary Reporting Program**

**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 November 29, 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 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Cosmetic Product Voluntary Reporting Program—21 CFR 720.4, 720.6, and 720.8(b) (OMB Control Number 0910-0030—Extension)**

Under the Federal Food, Drug, and Cosmetic Act (the act), cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) cannot legally be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, FDA requests under part 720 (21 CFR part 720), but does not require, that firms that manufacture, pack, or distribute cosmetics file with the agency an ingredient statement for each of their products (§ 720.4). Ingredient statements for new submissions (§ 720.1) are reported on Form FDA 2512 entitled "Cosmetic Product Ingredient Statement," and Form FDA 2512a, a

continuation form. Changes in product formulation (§ 720.6) are also reported on Forms FDA 2512 and FDA 2512a. When a firm discontinues the commercial distribution of a cosmetic, FDA requests that the firm file Form FDA 2514 entitled "Discontinuance of Commercial Distribution of Cosmetic Product Formulation" (§ 720.6). If any of the information submitted on or with these forms is confidential, the firm may submit a request for confidentiality under § 720.8.

FDA uses the information received on these forms as input for a computer-based information storage and retrieval system. These voluntary formula filings provide FDA with the best information available about cosmetic product formulations, ingredients and their frequency of use, businesses engaged in the manufacture and distribution of cosmetics, and approximate rates of product discontinuance and formula modifications. FDA's data base also lists cosmetic products containing ingredients suspected to be carcinogenic or otherwise harmful to the general public health. The information provided under the Cosmetic Product Voluntary Reporting Program assists FDA scientists in evaluating reports of alleged injuries and adverse reactions to the use of cosmetics. The information also is utilized in defining and planning analytical and toxicological studies pertaining to cosmetics.

FDA shares nonconfidential information from its files on cosmetics with consumers, medical professionals, and industry. For example, by submitting a Freedom of Information Act request, consumers can obtain information about which products do or do not contain a specified ingredient and about the levels at which certain ingredients are typically used. Dermatologists use FDA files to cross-reference allergens found in patch-test kits with cosmetic ingredients. The Cosmetic, Toiletry, and Fragrance Association, which is conducting a review of ingredients used in cosmetics, has relied on data provided by FDA in selecting ingredients to be reviewed based on frequency of use.

The Cosmetic Product Voluntary Reporting Program was suspended during fiscal year (FY) 1998 because of a lack of funding and was reinstated at the beginning of FY 1999. Participation returned to the previous level. Thus, FDA estimates that the burden of this collection of information will remain the same as the estimate presently on file with OMB.

In the **Federal Register** of August 9, 1999 (64 FR 43188), the agency requested comments on the proposed

collections of information. One

comment was received in support of the continuation of the program.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
720.4 (New submissions)	FDA 2512/ FDA 2512a	550	4.2	2,310	0.5	1,155
720.6 (Amendments)	FDA 2512/ FDA 2512a	550	1.4	770	0.33	254
720.6 (Notices of discontinuance)	FDA 2514	550	4.5	2,500	0.1	250
720.8 (Requests for confidentiality)		2	1.0	2	1.5	3
Total						1,662

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

This estimate is based on the number and frequency of submissions received in the past and on discussions between FDA staff and respondents during routine communications. The actual time required for each submission will vary in relation to the size of the company and the breadth of its marketing activities.

Dated: October 21, 1999.

**William K. Hubbard,**

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

[FR Doc. 99-28111 Filed 10-27-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99F-4373]

#### Engelhard Corp.; Filing of Food Additive Petition

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Engelhard Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a solid solution of 2-naphthalenesulfonic acid, 5-[(5-chloro-4-methyl-2-sulfophenyl)azo]-6-hydroxy]-, strontium salt (1:1) and 2-naphthalenesulfonic acid, 5-[(4-chloro-5-ethyl-2-sulfophenyl)azo]-6-hydroxy]-, strontium salt (1:1) (C.I. Pigment Red 276) as a colorant for polymers intended for food-contact applications.

**FOR FURTHER INFORMATION CONTACT:**

Mark Hepp, Center for Food Safety and Applied Nutrition (HFS-215), Food and

Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3098.

**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 9B4698) has been filed by Engelhard Corp., Pigments and Additives Group, 3400 Bank St., Louisville, KY 40212. The petition proposes to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of a solid solution of 2-naphthalenesulfonic acid, 5-[(5-chloro-4-methyl-2-sulfophenyl)azo]-6-hydroxy]-, strontium salt (1:1) and 2-naphthalenesulfonic acid, 5-[(4-chloro-5-ethyl-2-sulfophenyl)azo]-6-hydroxy]-, strontium salt (1:1) (C.I. Pigment Red 276) as a colorant for polymers intended for food-contact applications.

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: September 30, 1999.

**Laura M. Tarantino,**

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

[FR Doc. 99-28114 Filed 10-27-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99D-2335]

#### Medical Gloves; Draft Guidance Manual; Availability; Extension of Comment Period

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

**ACTION:** Notice of availability; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to January 27, 2000, the comment period for the draft guidance entitled "Medical Glove Guidance Manual." FDA published a notice of availability of the draft guidance in the **Federal Register** of July 30, 1999 (64 FR 41744). The agency is taking this action to harmonize the comment period for the draft guidance with the extension of the comment period for the proposed rule on the reclassification of surgeon's and patient examination gloves (64 FR 41710, July 30, 1999). The document announcing the extension of that comment period for the proposed rule is published elsewhere in this issue of the **Federal Register**. The draft guidance is a proposed special control for that reclassification. This extension of the comment period is intended to allow interested persons additional time to submit comments on the draft guidance.

**DATES:** Written comments by January 27, 2000.

**ADDRESSES:** 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.