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

[1]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]

BILLING CODE 4160–01–F

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]

BILLING CODE 4160–01–F

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.