

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

¹There 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.

FOR FURTHER INFORMATION CONTACT: Arthur K. Yellin, Center for Devices and Radiological Health (HFZ-200), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 800-638-2041, ext. 146 or 301-443-6597, ext. 146.

SUPPLEMENTARY INFORMATION:

I. Extension of Comment Period

In the **Federal Register** of July 30, 1999, FDA published a notice of availability of the draft guidance entitled "Medical Glove Guidance Manual." The draft guidance is intended to provide current information to assist manufacturers and others in obtaining marketing clearance, applying manufacturing and design controls, and properly labeling medical gloves. FDA also proposes to use the "Medical Glove Guidance Manual" as a special control in its proposed reclassification of surgeon's and patient examination gloves (64 FR 41710 at 41714).

Elsewhere in this issue of the **Federal Register**, FDA is announcing an extension of the comment period for the proposed rule on the reclassification of surgeon's and patient examination gloves. Because FDA has proposed that the "Medical Glove Guidance Manual" be a special control in that proposed reclassification, FDA wanted to harmonize the comment periods. Consequently, FDA is extending the

comment period on the draft guidance for 90 additional days.

II. Comments

Interested persons may, on or before January 27, 2000, submit to the Dockets Management Branch (address above) written comments regarding the draft guidance. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 21, 1999.
Margaret M. Dotzel,
Acting Associate Commissioner for Policy.
 [FR Doc. 99-28110 Filed 10-27-99; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request NIH Intramural Research Training Award, Program Application

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the

Office of the Director, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: NIH Intramural Research Training Award, Program Application; *Type of Information Collection Request:* Revision/OMB No. 0925-0299; 4/30/2000; *Need and Use of Information Collection:* The proposed information collection activity is for the purpose of collecting data related to the availability of Training Fellowships under the HIH Intramural Research Training Award Program. This information must be submitted in order to receive due consideration or an award and will be used to determine the eligibility and quality of potential awardees. *Frequency of Response:* On occasion. *Affected Public:* Individuals seeking Intramural Training award opportunities. *Type of Respondents:* Postdoctoral, Predoctoral, Post-baccalaureate, Technical, and Student IRTA applicants. *Estimated Number of Respondents:* 15779. *Estimated Number of Responses Per Respondent:* 1. *Average Burden Hours Requested:* .53. *Estimated Total Annual Burden Hours Requested:* 8422.

There are no Capital Costs, Operating Costs, and/or Maintenance Costs of report.

Type of respondent	Estimated number for respondents	Estimated numbers of respondents per respondent	Average burden hours per response	Estimated total annual burden hours requested
Postdoctoral IRTA	1089	1	1	1089
Predoctoral IRTA	6	1	1	6
Postbaccalaureate IRTA	290	1	1	290
Technical IRTA	27	1	1	27
Student IRTA	3,386	1	1	27
References for all IOTA categories	10,98133	3,624
Total	15779	1	.53	8,422

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and the clarity of information to be collected; and (4) Ways to minimize the

burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Edie Bishop, Human Resource Consultant, Office of Human Resource Management, OD, NIH, Building 31, Room B3C07, 31 Center Drive MSC. 2203, Bethesda, MD 20892-2203.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before December 27, 1999.

Dated: October 20, 1999.
Stephen C. Benowitz,
Director, Office of Human Resource Management.
 [FR Doc. 99-28270 Filed 10-27-99; 8:45 am]
BILLING CODE 4140-01-M