

stabilizer, and texturizer in cream liqueur drinks.

**FOR FURTHER INFORMATION CONTACT:**

Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3072.

**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 9A4684) has been filed by American Ingredients Co., 3947 Broadway, Kansas City, MO 64111. The petition proposes to amend the food additive regulations in § 172.846 *Sodium stearoyl lactylate* (21 CFR 172.846) to provide for the expanded safe use of sodium stearoyl lactylate as an emulsifier, stabilizer, and texturizer in cream liqueur drinks.

The agency has determined under 21 CFR 25.32(k) that this action is of a 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: August 31, 1999.

**Alan M. Rulis,**

*Director, Office of Premarket Approval,  
Center for Food Safety and Applied Nutrition.*  
[FR Doc. 99-23682 Filed 9-10-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99F-2997]

#### 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 1-naphthelenesulfonic acid, 2-[(4,5-dihydro-3-methyl-5-oxo-1-(3-Sulfophenyl)-1H-pyrazol-4-yl)azo]-, strontium and calcium salt (1:1) (C.I. Pigment 209 and C.I. Pigment 209:1) as colorants 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 9B4691) 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 1-naphthelenesulfonic acid, 2-[(4,5-dihydro-3-methyl-5-oxo-1-(3-Sulfophenyl)-1H-pyrazol-4-yl)azo]-, strontium and calcium salt (1:1) (C.I. Pigment 209 and C.I. Pigment 209:1) as colorants for polymers intended for food-contact applications. The agency has determined under 21 CFR 25.32(i) that this action is of a 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: August 25, 1999

**Alan M. Rulis**

*Director, Office of Premarket Approval,  
Center for Food Safety and Nutrition*  
[FR Doc. 99-23664 Filed 9-10-99; 8:45 am]  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98D-0656]

#### Guidance for Industry on Submission of Abbreviated Reports and Synopses in Support of Marketing Applications; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Submission of Abbreviated Reports and Synopses in Support of Marketing Applications." This guidance, which implements section 118 of the Food and Drug Administration Modernization Act of 1997 (Modernization Act), is intended to assist applicants who wish to submit abbreviated reports and synopses in lieu of full reports for certain clinical studies, both in marketing applications for new products and in supplements to approved applications. The guidance describes which studies may be submitted as abbreviated reports or synopses and describes a format for such submissions.

**DATES:** General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of this guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/guidelines.htm>. Submit written requests for single copies of the guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or the Manufacturers Assistance and Communication Staff (HFM-42), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Comments are to be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Debbie J. Henderson, Center for Drug Evaluation and Research (HFD-6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-6779.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 21, 1998 (63 FR 50251), FDA announced the availability of a draft version of this guidance for industry entitled "Submission of Abbreviated Reports and Synopses in Support of Marketing Applications." The agency has finalized that draft guidance after considering comments received on the draft version. Only few comments were received, and minor changes were made to the draft version in an effort to make the document clearer.

This guidance implements section 118 of the Modernization Act, "Data requirements for drugs and biologics," which directs FDA to issue guidance on when abbreviated study reports may be submitted in new drug applications (NDA's) and biologics license applications (BLA's) in lieu of full reports. Applicants have experienced difficulties in the past in deciding when a full study report is required by the reviewing body. For example, clinical drug and biologic product development programs often include numerous clinical studies and resulting data that are not intended to contribute to the evaluation of the effectiveness of a product for a particular use and are not needed to support information included

in labeling. Accordingly, such studies may be submitted as abbreviated reports or synopses, and this guidance is intended to facilitate their submission. This guidance is intended to provide guidance on the types of studies that may be submitted in abbreviated reports or synopses. The guidance also provides recommendations on the formats that should be used.

In the **Federal Register** of September 21, 1998 (63 FR 50241), FDA announced that it was submitting to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA) the collection of information entitled "Application for FDA Approval to Market a New Drug—21 CFR Part 314—(OMB Control Number 0910-0001)." In that notice, FDA stated that the draft guidance entitled "Submission of Abbreviated Reports and Synopses in Support of Marketing Applications" (a notice announcing the availability of the draft guidance was published in the same issue of the **Federal Register**) would reduce the industry burden for submitting marketing applications under § 314.56 (21 CFR 314.50). FDA estimated that this reduction in burden would be approximately 300 hours, and reduced the industry burden estimate for § 314.50 accordingly. The **Federal Register** notice also requested comments on the burden estimates for part 314 (21 CFR part 314). OMB received no comments on the notice and approved the information collection for part 314 until November 30, 2001. In addition, none of the comments received in response to the notice announcing the availability of the draft guidance pertained to information collection issues under the PRA.

This guidance represents the agency's current thinking on submission of full study reports, abbreviated reports, and synopses of information related to effectiveness for new drugs and biological products. 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 statutes, regulations, or both.

Interested persons may submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 19, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 99-23663 Filed 9-10-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Program Support Center; Agency Information Collection Activities: Proposed Collections; Comment Request

The Department of Health and Human Services, Program Support Center (PSC), will periodically publish summaries of proposed information collection projects and solicit public comments in compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request more information on the project or to obtain a copy of the information collection plans and instruments, call the PSC Reports Clearance Officer on (301) 443-2045.

*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

1. HHS Payment Management System Forms (PSC-270, formerly PMS-270) and (PSC-272, formerly PMS-272)—0937-0200—Extension

The PSC-270 (formerly PMS-270), Request for Advance or Reimbursement is used to make advances or reimbursement payments to grantees. It serves in place of the SF-270. Respondents: State and local governments; profit and nonprofit businesses and organizations receiving grants for HHS; Total Number of Respondents: 10; Frequency of Response: monthly; Average Burden per Response: 15 minutes; Estimated Annual Burden: 30 hours.

The PSC-272 (formerly PMS-272), Federal Cash Transactions Report, is used to monitor Federal cash advances to grantees and obtain Federal cash disbursement data. It serves in place of the SF-272. Respondents: State and local governments, profit and nonprofit businesses and institutions receiving

grants from HHS; Total Number of Respondents: 16,800; Frequency of Response: quarterly; Average Burden per Response: 4 hours; Estimated Annual Burden: 268,800 hours.

Total Burden: 268,830 hours.

Send comments to Norman E. Prince, Jr., Acting PSC Reports Clearance Officer, Room 17A08, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: September 3, 1999.

**Lynnda M. Regan,**

*Director, Program Support Center.*

[FR Doc. 99-23666 Filed 9-10-99; 8:45 am]

BILLING CODE 4168-17-M

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Notice to Reopen the Public Comment Period for the Draft Recovery Plan for the Giant Garter Snake (*Thamnophis gigas*)

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of reopening of public comment period.

**SUMMARY:** The U.S. Fish and Wildlife Service gives notice that the comment period announced in the July 2, 1999 (64 FR 36033), notice of availability of the Draft Recovery Plan for the Giant Garter Snake (*Thamnophis gigas*) will be reopened for an additional 30 days. Substantial public interest in the draft plan led the Service to distribute additional copies and to provide additional opportunities for the public to comment on the plan. This draft recovery plan contains recovery criteria and actions for threatened giant garter snake. Additional species of concern that will benefit from recovery actions taken for the giant garter snake are also discussed in the draft plan. The Service reopens the comment period and solicits review and comment from the public on this draft plan.

**DATE:** Comments on the draft recovery plan received by October 13, 1999 will be considered by the Service.

**ADDRESSES:** Copies of the draft recovery plan are available for inspection, by appointment, during normal business hours at the following location: U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office, 2800 Cottage Way, W-2605, Sacramento, California (telephone (916) 414-6600); and U.S. Fish and Wildlife Service, Regional Office, Ecological Services, 911 NE. 11th Avenue, Eastside Federal Complex,