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-Sulfopheny)-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-Sulfopheny)-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]

BILLING CODE 4160–01–F

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