stabilizer, and texturizer in cream liqueur drinks.

FOR FURTHER INFORMATION CONTACT:

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(h) 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.

Alan M. Rulis, Director, Office of Premarket Approval, Center for Food Safety and Nutrition.

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-naphthlenesulfonic 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(h) 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Notice of September 13, 1999]

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-naphthlenesulfonic 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.


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