

resulting from severe storms, straight-line winds, and flooding beginning on July 4, 1999 and continuing through July 31, 1999, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, Pub. L. 93-288, as amended ("the Stafford Act"). I, therefore, declare that such a major disaster exists in the State of Wisconsin.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation in the designated areas and any other forms of assistance under the Stafford Act you may deem appropriate. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance or Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Thomas Davies of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Wisconsin to have been affected adversely by this declared major disaster:

Ashland, Bayfield, Douglas, Florence, Iron, Oneida, Price, Rusk, Sawyer, and Vilas Counties for Public Assistance.

All counties within the State of Wisconsin are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program)

James L. Witt,

Director.

[FR Doc. 99-23733 Filed 9-10-99; 8:45 am]

BILLING CODE 6718-02-PS4703

FEDERAL RESERVE SYSTEM

Federal Open Market Committee; Domestic Policy Directive of June 29-30, 1999.

In accordance with § 271.5 of its rules regarding availability of information (12 CFR part 271), there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on June 29-30, 1999.¹ The directive was issued to the Federal Reserve Bank of New York as follows:

The information reviewed at this meeting suggests continued vigorous expansion in economic activity. Nonfarm payroll employment has increased at a relatively rapid pace in recent months and the civilian unemployment rate, at 4.2 percent in May, matched its low for the year. Manufacturing output rose substantially further in May. Total retail sales increased briskly last month after recording large gains on average earlier in the year. Housing activity has remained robust in recent months. Available indicators suggest that business capital spending, especially for information technology, has accelerated this spring. The nominal deficit on U.S. trade in goods and services widened somewhat in April from its first-quarter average. Consumer price inflation was up somewhat on balance in April and May, boosted by a sharp increase in energy prices; improving productivity has held down increases in unit labor costs despite very tight labor markets.

Interest rates have risen somewhat since the meeting on May 18, 1999. Key measures of share prices in equity markets are unchanged to somewhat lower on balance over the intermeeting period. In foreign exchange markets, the trade-weighted value of the dollar has changed little over the period in relation to the currencies of a broad group of important U.S. trading partners.

After recording sizable increases in April, apparently owing to a tax-related buildup in liquid accounts, growth of M2 and M3 slowed in May as tax payments cleared and appears to have remained moderate in June. For the year through June, M2 is estimated to have increased at a rate somewhat above the Committee's annual range and M3 at a rate near the upper end of its range. Total domestic nonfinancial debt has

¹ Copies of the Minutes of the Federal Open Market Committee meeting of June 29-30, 1999, which include the domestic policy directive issued at that meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, D.C. 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's annual report.

continued to expand at a pace somewhat above the middle of its range.

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. In furtherance of these objectives, the Committee reaffirmed at this meeting the ranges it had established in February for growth of M2 and M3 of 1 to 5 percent and 2 to 6 percent respectively, measured from the fourth quarter of 1998 to the fourth quarter of 1999. The range for growth of total domestic nonfinancial debt was maintained at 3 to 7 percent for the year. For 2000, the Committee agreed on a tentative basis to set the same ranges for growth of the monetary aggregates and debt, measured from the fourth quarter of 1999 to the fourth quarter of 2000. The behavior of the monetary aggregates will continue to be evaluated in the light of progress toward price level stability, movements in their velocities, and developments in the economy and financial markets.

To promote the Committee's long-run objectives of price stability and sustainable economic growth, the Committee in the immediate future seeks conditions in reserve markets consistent with increasing the federal funds rate to an average of around 5 percent. In view of the evidence currently available, the Committee believes that prospective developments are equally likely to warrant an increase or a decrease in the federal funds rate operating objective during the intermeeting period.

By order of the Federal Open Market Committee, September 3, 1999.

Donald L. Kohn,

Secretary, Federal Open Market Committee.

[FR Doc. 99-23690 Filed 9-10-99; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F-3087]

American Ingredients Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that American Ingredients Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of sodium stearoyl lactylate as an emulsifier,

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-naphthalenesulfonic 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-naphthalenesulfonic 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]

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