

Dated: February 26, 1999.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99-6533 Filed 3-17-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F-0459]

Exxon Co. International; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Exxon Co. International has filed a petition proposing that the food additive regulations be amended to provide for the safe use of isopropyl laurate in surface lubricants used in the manufacture of metallic articles intended for contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

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 9B4647) has been filed by Exxon Co. International, 200 Park Ave., Florham Park, NJ 07932-1002. The petition proposes to amend the food additive regulations in § 178.3910 *Surface lubricants used in the manufacture of metallic articles* (21 CFR 178.3910) to provide for the safe use of isopropyl laurate in surface lubricants used in the manufacture of metallic articles intended for contact with food.

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: February 26, 1999.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F-0345]

UCB Films PLC; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that UCB Films PLC has filed a petition proposing that the food additive regulations be amended to provide for the safe use of mono- and bis-(octadecyldiethyleneoxide)phosphates as components of coatings on cellophane intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

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 9B4642) has been filed by UCB Films PLC, c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 177.1200 *Cellophane* (21 CFR 177.1200) to provide for the safe use of mono- and bis-(octadecyldiethyleneoxide)phosphates as components of coatings on cellophane intended for use in contact with food.

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: February 26, 1999.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting is open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 22 and 23, 1999, 8 a.m. to 5 p.m.

Location: Pook's Hill Marriott, Ballroom, 5151 Pook's Hill Rd., Bethesda, MD.

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 22, 1999, the committee will discuss the safety and efficacy of new drug application (NDA) 21-071, Avandia™ (rosiglitazone, SmithKline Beecham) for the treatment of hyperglycemia in type 2 diabetes mellitus, as monotherapy and in combination with metformin. On April 23, 1999, the committee will discuss the safety and efficacy of NDA 21-073, Actos™ (pioglitazone, Takeda Pharmaceuticals) to improve glycemic control in patients with type 2 diabetes mellitus.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 14, 1999. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 14, 1999, and