

product Acellular Pertussis Toxoid Adsorbed to Denmark for further shipment to Sweden. The Pertussis component is an acellular monocomponent vaccine containing inactivated pertussis toxin. The application was received and filed in the Center for Biologics Evaluation and Research on February 8, 1996, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by March 14, 1996, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Biologics Evaluation and Research (21 CFR 5.44).

Dated: February 16, 1996.

James C. Simmons,

Director, Office of Compliance, Center for Biologics Evaluation and Research.

[FR Doc. 96-4978 Filed 3-1-96; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 96F-0062]

Cytec Industries Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Cytec Industries Inc. has filed a petition proposing that the food additive regulations be amended to correct nomenclature. The amendment would change the two listings for sulfosuccinic acid 4-ester with polyethylene glycol dodecyl ether, disodium salt (CAS Reg. No. 39354-45-5) to polyethyleneglycol alkyl (C10-C12) ether sulfosuccinate, disodium salt (CAS Reg. No. 68954-91-6).

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food

Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-606-0202.

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 6B4485) has been filed by Cytec Industries Inc., c/o Keller and Heckman, 1001 G St., NW., suite 500 West, Washington, DC 20001. The petition proposes that the food additive regulations in §§ 175.105 Adhesives (21 CFR 175.105) and 178.3400 Emulsifiers and/or surface-active agents (21 CFR 178.3400) be amended to correct nomenclature. The amendment would change the two listings for sulfosuccinic acid 4-ester with polyethylene glycol dodecyl ether, disodium salt (CAS Reg. No. 39354-45-5) to use the nomenclature polyethyleneglycol alkyl (C10-C12) ether sulfosuccinate, disodium salt (CAS Reg. No. 68954-91-6). The agency has determined under 21 CFR 25.24(a)(9) 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 9, 1996.

Alan M. Rulis,

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

[FR Doc. 96-4976 Filed 3-1-96; 8:45 am]

BILLING CODE 4160-01-F

Product and Establishment License Applications, Refusal to File; Meeting of Oversight Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of its standing oversight committee in the Center for Biologics Evaluation and Research (CBER) that conducts a periodic review of CBER's use of its refusal to file (RTF) practices on product license applications (PLA's) and establishment license applications (ELA's). CBER's RTF oversight committee examines all RTF decisions that occurred during the previous quarter to assess consistency across CBER offices and divisions in RTF decisions.

DATES: The meeting will be held in April 1996.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics

Evaluation and Research (HFM-4), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0379.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 15, 1995 (60 FR 25920), FDA announced the establishment and first meeting of CBER's standing oversight committee. As explained in the notice, the importance to the public health of getting new biological products on the market as efficiently as possible has made improving the biological product evaluation process an FDA priority. CBER's managed review process focuses on specific milestones or intermediate goals to ensure that a quality review is conducted within a specified time period. CBER's RTF oversight committee meetings continue CBER's effort to promote the timely, efficient, and consistent review of PLA's and ELA's.

FDA regulations on filing PLA's and ELA's are found in 21 CFR 601.2(a) and 601.3. A sponsor who receives an RTF notification may request an informal conference with CBER, and thereafter may ask that the application be filed over protest, similar to the procedure for drugs described under 21 CFR 314.101(a)(3) (see 57 FR 17950, April 28, 1992).

CBER's standing RTF oversight committee consists of senior CBER officials, a senior official from FDA's Center for Drug Evaluation and Research, and FDA's Chief Mediator and Ombudsman. Meetings, ordinarily, will be held once a quarter to review all of the RTF decisions. The purpose of such a review is to assess the consistency within CBER in rendering RTF decisions.

Because the committee's deliberations will deal with confidential commercial information, all meetings will be closed to the public. The committee's deliberations will be reported in the minutes of the meeting. Although those minutes will not be publicly available because they will contain confidential commercial information, summaries of the committee's deliberations, with all confidential commercial information omitted, may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If, following the committee's review, an RTF decision changes, the appropriate division will notify the sponsor.