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.

Dated: February 27, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–4913 Filed 3–1–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0409]

Alternative and Traditional Models for Safety Evaluation of Food Ingredients; Announcement of Study; Request for Scientific Data and Information; Announcement of Open Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) will undertake a comprehensive discussion of the scientific criteria and principles generally agreed upon by scientists in the food safety community as necessary for demonstrating that a food ingredient is safe. This discussion will include both a description of the data needed to ensure safety or to achieve a reasonable certainty that the ingredient will not cause harm and alternative approaches for achieving that assurance when traditional approaches do not definitively resolve safety questions.

To assist in the preparation of a scientific report, LSRO/FASEB is inviting the submission of scientific data and information regarding this topic. LSRO/FASEB will provide an opportunity for oral presentations at an open meeting.

DATES: LSRO/FASEB has scheduled a 1-day public meeting on this topic for May 15, 1996. Requests to make oral presentations at the open meeting must be submitted in writing and received by April 24, 1996. Submit written presentations of scientific data, information, and views on or before May 10, 1996.

ADDRESSES: Submit written requests to make oral presentations at the open meeting to both the Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20814–3998 and to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of the scientific data, information, and views for presentation should be submitted to each office. The meeting will be held in the Chen Auditorium, Lee Bldg., FASEB (address above).

FOR FURTHER INFORMATION CONTACT: Daniel J. Raiten or Sue Ann Anderson, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20814–3998, 301–530–7030, on the scheduling of presentations at the public meeting and related matters. Other information may be obtained from Victor Frattali, Center for Food Safety and Applied Nutrition (HFS–2), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–1730.

SUPPLEMENTARY INFORMATION: FDA has a contract (223–92–2185) with LSRO/FASEB concerning the analysis of scientific issues that bear on the safety of foods and cosmetics. The objectives of this contract are to provide information to FDA on general and specific issues of scientific fact associated with the analysis of human nutrition.

As one task under the contract, FDA has requested information on matters related to the adequacy of data needed to support decisions on the safety of food ingredients. Currently, FDA provides safety testing guidelines for food ingredients through a publication entitled ''Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food'' (also known as the ''Redbook''). This document gives guidance to petitioners primarily for those situations in which a traditional approach to safety testing is appropriate (i.e., those in which food additives to be used in low concentrations are tested for safety).

However, traditional studies involving administration of substances constituting a large part of an animal's diet may produce adverse effects simply as a result of the unusual diet rather than the inherent toxicity of the test substance. Further, FDA recognizes that the advent of new technologies such as genetic engineering of traditional foods and novel uses of plant products, as well as development of macroingredients, present new situations for which an alternative approach to safety assessment may be needed. While FDA has successfully reached decisions on food ingredients produced with such new technologies on a case-by-case basis, it has become clear that a need exists for information on the criteria that the scientific community believes are appropriate so that both a requirement for new types of safety studies and any elimination or limitation of the role of traditional studies can be justified. Types of food ingredients for which an alternative model may be appropriate include, for example, macroingredient substitutes such as psyllium, ingredients derived from botanicals such as *Stevia rebaudiana Bertoni*, restructured fats such as caprenin, and ingredients derived using biotechnology.

Based on an evolving need to be responsive to the development of food ingredients resulting from new technologies, FDA wishes to have LSRO/FASEB prepare a comprehensive report on the principles and criteria generally agreed upon by the community of food safety experts for determining when the traditional safety model is appropriate. The agency is also interested in a discussion identifying the principles and criteria to be used to determine the safety of a food ingredient when the traditional safety model is not appropriate. FDA is especially interested in a discussion of how different principles and criteria should be ranked and weighted, interrelationships that should be considered, and any situation where a principle or criterion might be considered determinative without regard to other considerations. It would also be desirable to have a discussion about how the new testing approaches may substitute for more traditional testing.

In framing this discussion, FDA has suggested that the following questions be considered. These questions are not intended as a statement of specific tasks. They are intended to be illustrative and to be used as a basis for stimulating thinking regarding the determination of the safe use of food ingredients.

1. In what cases, if any, are animal feeding studies not necessary to ensure safety? For example: Do such studies need to be conducted for ingredients that also occur naturally in foods at similar or higher concentrations? Is it reasonable and necessary to test food-like substances for toxicity and nutritional influences recognizing the potential for confounding results? If so, how?

2. To what extent can chemical and structural similarity to food ingredients known to be safe obviate the need for animal or human testing?

3. What criteria should be used to determine when a treatment-related effect (including effects from nutritional imbalance or interference) is an adverse effect?

4. Are there criteria that can be used to determine whether an adverse effect observed in a study is relevant to human safety as opposed to an effect that is dependent on study design and has no