

timely manner any new data concerning the abuse potential of the drug under evaluation that may become available. As discussed above, appropriate clearances must be secured before data may be shared with NIDA.

2. Drug products not subject to a pending NDA: When a domestic drug scheduling question arises other than in connection with FDA review of a pending NDA, FDA will inform NIDA of the scheduling issue and will invite NIDA to participate in the evaluation process.

3. In all situations covered by Part A of this agreement, FDA will make available to NIDA a copy of its proposed draft scheduling recommendation.

B. *Consideration of Draft Scheduling Recommendations by the FDA Drug Abuse Advisory Committee (DAAC).* 1. The Executive Secretary of DAAC will notify NIDA when a scheduling matter has been placed on a DAAC meeting agenda and will provide NIDA a copy of the agenda as soon as it is available.

2. Data provided to DAAC to assist in its deliberation on a drug scheduling matter will be made available to the NIDA representative at the same time they are made available to the DAAC members. The NIDA representative shall have secured any necessary FDA conflict-of-interest clearance in advance of receipt of these data or authorization to release the data will be secured from the NDA sponsor.

3. NIDA will provide DAS any comments or specific data it has regarding an agenda item as far in advance of the meeting as possible so that NIDA's comments and data can be sent to the DAAC members for review prior to the meeting.

4. NIDA may indicate its desire to make a formal presentation to DAAC on any drug scheduling item that is part of the scheduled agenda for a DAAC meeting. Such a presentation would normally consist of at least one of the following:

a. A response to a general question concerning drug scheduling. (DAS should have received a copy of the data NIDA will present—see B.3. above.)

b. Results of an independent evaluation conducted by NIDA. The presentation should emphasize NIDA's additional data or different points of view from those of FDA. Data should be provided in advance to DAS—see B.3. above.)

c. A statement that NIDA has determined to present no data.

C. *Review of Final Draft Scheduling Recommendations.* 1. After the DAAC meeting, a proposed final scheduling recommendation will be drafted by and circulated within CDB. A copy of the draft recommendation will promptly be provided to NIDA for comment.

2. If the CDB draft scheduling recommendation is substantially revised by FDA, a copy of the revised document will be transmitted to NIDA for further comment.

3. If NIDA does not concur in the final recommendation before it is submitted to the FDA Commissioner for signature, NIDA should specify its nonconcurrency to the FDA Commissioner in writing. The data upon which NIDA's position is based should be included in this document.

4. If disagreement between the agencies cannot be resolved, the NIDA dissent will be forwarded to the ASH concurrently with FDA's scheduling recommendations.

IV. Name and Address of Participating Parties

A. Food and Drug Administration, Public Health Service, Department of Health and Human Services, 5600 Fishers Lane, Rockville, MD 20857.

B. National Institute on Drug Abuse, Public Health Service, Department of Health and Human Services, 5600 Fishers Lane, Rockville, MD 20857.

V. Liaison Officers

A. For Food and Drug Administration: Associate Commissioner for Health Affairs (currently Stuart L. Nightingale, M.D., 301-443-6143).

B. For National Institute on Drug Abuse: Associate Director for Medical and International Affairs (currently James R. Cooper, M.D.), 301-443-4877.

VI. Period of Agreement

This agreement becomes effective upon acceptance by both parties. It may be modified by mutual consent or terminated by either party upon the giving of a 60-day written notice.

Approved and accepted for the Food and Drug Administration.

By: Mark Novitch,

Title: Deputy Commissioner.

Date: November 13, 1984.

Approved and accepted for the National Institute on Drug Abuse.

By: William Pollin,

Title: Director.

Date: December 11, 1984.

Effective date. This memorandum of understanding became effective December 11, 1984.

Dated: March 4, 1985.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-5550 Filed 3-7-85; 8:45 am]

BILLING CODE 4160-01-M

[FDA-225-85-0001]

Memorandum of Understanding With the University of Tennessee

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has executed a memorandum of understanding with the University of Tennessee. This agreement provides the mechanism for collaborative research and educational programs between the University of Tennessee through its Center for Health Sciences (UTCHS) and FDA's National Center for Toxicological Research (NCTR).

DATE: This agreement became effective December 17, 1984.

FOR FURTHER INFORMATION CONTACT: Walter J. Kustka, Intergovernmental and Industry Affairs Staff (HFC-50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1583.

SUPPLEMENTARY INFORMATION: In accordance with § 20.108(c) (21 CFR 20.108(c)) which states that all agreements and memoranda of understanding between FDA and others shall be published in the *Federal Register*, the agency is publishing the following memorandum of understanding:

Memorandum of Understanding Between the University of Tennessee, Memphis, Tennessee and the Food and Drug Administration, National Center for Toxicological Research

I. Purpose

This agreement provides the mechanism for collaborative research and educational programs between the University of Tennessee through its Center for Health Sciences (UTCHS) and the Food and Drug Administration's National Center for Toxicological Research (NCTR).

II. Background

The University of Tennessee Center for the Health Sciences is a public institution within the University of Tennessee system which has an enrollment of some 42,500 students. UTCHS is composed of the Colleges of Community and Allied Health Professions, Dentistry, Medicine, Nursing, and Pharmacy, as well as the Graduate School of Medical Sciences. There are approximately 2,000 students in these advance programs at UTCHS. One of the major objectives of the professional programs of the University is to produce graduates who are well prepared and highly motivated to pursue advanced work in the sciences.

The National Center for Toxicological Research is a Federal laboratory specializing in biomedical research. A part of NCTR's goal is to assist in training highly qualified toxicologists. The collaborative program with UTCHS provides an opportunity to accomplish this while furthering NCTR's research goals.

III. Substance of Agreement

Through this agreement, NCTR will provide facilities, equipment, materials, and limited supervision for outstanding science students who will serve as guest workers at the Center performing collaborative research with NCTR scientists. In addition, NCTR will provide guest worker positions or appointments to do collaborative research for qualified faculty members of UTCHS, if spaces are available during summers, periods of sabbatical leave, or other mutually agreeable periods.

NCTR and UTCHS will establish cooperative scientific activities, which may include joint guest lectures and seminar programs, for the benefit of all members of

both institutions to promote exchange of information on the latest developments at both institutions. To further accomplish this objective, members of the staffs of NCTR and UTCHS will be granted access to the library facilities of both institutions.

IV. Name and Address of Participating Parties

- A. University of Tennessee Center for the Health Sciences, 600 Madison Ave., Memphis, TN 38163.
B. Food and Drug Administration, National Center for Toxicological Research, Jefferson, AR 72079.

V. Liaison Officers

- A. For University of Tennessee Center for the Health Sciences: Professor, Department of Medicinal Chemistry, College of Pharmacy (currently Dr. W. H. Lawrence), 901-528-8927 or 901-528-6080.
B. For the National Center for Toxicological Research: Director, National Center for Toxicological Research, (currently Dr. Ronald W. Hart), 501-541-4517.

VI. Period of Agreement

This agreement becomes effective upon acceptance by both parties and will continue indefinitely. It may be modified by mutual consent or terminated by either party upon a 60-day advance written notice to the other.

Approved and accepted for the University of Tennessee.

By: James C. Hunt,

Title: Chancellor.

Date: November 23, 1984.

By: Emerson H. Fly,

Title: Vice President.

Date: December 17, 1984.

Approved and accepted for the Food and Drug Administration.

By: Joseph P. Hile,

Title: Associate Commissioner for Regulatory Affairs.

Date: October 5, 1984.

Effective date. This memorandum of understanding became effective December 17, 1984.

Dated: March 4, 1985.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-5532 Filed 3-7-85; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 85F-0060]

UBE Industries, Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Springborn Regulatory Services, Inc., on behalf of Ube Industries, Ltd., has filed a petition proposing that the

food additive regulations be amended to provide for the safe use of polyamides consisting of the homopolymer of Nylon 12 derived from omega-aminododecanoic acid as side seam cements that may contact food.

FOR FURTHER INFORMATION CONTACT: Thomas C. Brown, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 4B3796) has been filed by Springborn Regulatory Services, Inc., Enfield, CT 06082, on behalf of the Ube Industries, Ltd., Tokyo, Japan, proposing that the food additive regulations be amended to provide for the safe use of polyamides consisting of the homopolymer of Nylon 12 derived from omega-aminododecanoic acid as side seam cements that may contact food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: March 1, 1985.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-5547 Filed 3-7-85; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 85F-0082]

Economics Laboratory, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Economics Laboratory, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of decanoic acid, octanoic acid, a mixture of 1-octanesulfonic acid and 1-octanesulfonic-2-sulfonic acid, and the condensate of four moles of poly(oxyethylene)poly(oxypropylene) block copolymers with one mole of ethylenediamine as components of sanitizing solutions to be used on food-

processing equipment and other food-contact articles.

FOR FURTHER INFORMATION CONTACT: Mary W. Lipien, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 5H3842) has been filed by Economics Laboratory, Inc., St. Paul, MN 55102, proposing that the food additive regulations be amended to provide for the safe use of decanoic acid, octanoic acid, a mixture of 1-octanesulfonic acid and 1-octanesulfonic-2-sulfonic acid, and the condensate of four moles of poly(oxyethylene)poly(oxypropylene) block copolymers with one mole of ethylenediamine as components of sanitizing solutions to be used on food-processing equipment and other food-contact articles.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: March 1, 1985.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-5546 Filed 3-7-85; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 85F-0023]

Drew Chemical Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Drew Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of sorbitan monooleate as a direct additive to clarify cane and beet sugar juice and liquor.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 345(b)(5))), notice is given that a petition (FAP 5A3840) has been filed by Drew Chemical Corp., One Drew Chemical Plaza, Boonton, NJ 07005, proposing that the food additive regulations be amended to provide for the safe use of sorbitan monooleate as a direct additive to clarify cane and beet sugar juice and liquor.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: March 1, 1985.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-5545 Filed 3-7-85; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 85F-0057]

The Goodyear Tire & Rubber Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Goodyear Tire & Rubber Co. has filed a petition proposing that the food additive regulations be amended to include dimethyl-5-sulfoisophthalic acid, and/or its sodium salt, in the list of acids for polyester resins (including alkyd type) intended for use as components of adhesives in food-packaging applications.

FOR FURTHER INFORMATION CONTACT: Mary W. Lipien, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5), 72 Stat. 1786 (21 U.S.C. 345(b)(5))), notice is given that a petition (FAP 4B3825) has been filed by The Goodyear Tire & Rubber Co., 130 Johns Ave., Akron, OH 44316-0001, proposing that the food additive regulations be amended to include dimethyl-5-sulfoisophthalic acid, and/or its sodium salt, in the list of acids for polyester resins (including alkyd type) intended for use as components of

adhesives in food-packaging applications.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 1, 1985.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 85-5542 Filed 3-7-85; 8:45 am]

BILLING CODE 4160-01-M

Small Business Participation; Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a forthcoming small business exchange meeting to be chaired by George J. Gerstenberg, Director, Brooklyn District Office.

DATE: The meeting will be held at 1 p.m., Thursday, March 28, 1985.

ADDRESS: The meeting will be held at the Commack Public Library, 18 Hauppauge Rd., Commack, NY 11725.

FOR FURTHER INFORMATION CONTACT: George R. Walden, Small Business Representative, Food and Drug Administration, 20 Evergreen Place, East Orange, NJ 07018-2195, 201-645-6466.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between small business and FDA officials. The meeting will provide a forum for the owners and managers of small businesses to express their concerns about FDA, encourage discussion about the effects of regulation and regulatory alternatives, convey knowledge about the agency's operations and procedures, and increase participation by small business persons in FDA's decisionmaking process.

Dated: March 5, 1985.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-5543 Filed 3-7-85; 8:45 am]

BILLING CODE 4160-01-M

Health Resources and Services Administration

Application Announcement and Proposed Funding Preference for Grants for Geriatric Education Centers

The Bureau of Health Professions, Health Resources and Services Administration, announces the acceptance of applications for Fiscal Year 1985 Grants for Geriatric Education Centers under the authority of Section 788(b) of the Public Health Service Act, as amended by Pub. L. 97-35 and invites comments on the proposed funding preference as set forth below.

Grants will be awarded to support the development of additional areawide organizational arrangements called Geriatric Education Centers focused on strengthening and coordinating multidisciplinary training in geriatric health care involving several health professions. These centers are established to facilitate training of medical, dental, optometric, pharmacy, podiatric, nursing, and appropriate allied health and public health faculty, students, and practitioners in the diagnosis, treatment, and prevention of diseases and other health problems of the aged. To receive support, applicants must meet the requirements of 42 CFR Part 57, Subpart NN.

Functioning within a self-defined geographic area, which may be a metropolitan area, a State or portion thereof, or an area including all or part of two or more States, a Geriatric Education Center provides the health professions educational community within that area with comprehensive services such as:

1. Training which prepares faculty in the various health professions schools to carry out geriatric education programs;
2. Serving as a focal point for collection and dissemination of information on geriatric education programs and instructional materials;
3. Providing educational services, including consultation, in support of geriatric training of health professionals, to schools and programs, professional associations, and State, local, and voluntary agencies;
4. Assisting health professions schools in the selection, development, implementation, and evaluation of appropriate geriatric course materials and curriculum improvements; and
5. Assisting in the establishment of further organizational arrangements in other components of a health sciences center or among health professions educational programs to provide multidisciplinary resources for geriatric