[Docket No. 83N-0154]

International Drug Scheduling; Convention of Psychotropic Substances; Benzodiazepines

Correction

In FR Doc. 83-12844, beginning on page 21661, in the issue of Friday, May 13, 1983, on page 21662, in the first column, in the fourth complete paragraph, in the fourth line, "estaolam" should read "estazolam".

BILLING CODE 1505-01-M

[Docket No. 83F-0157]

Ciba-Geigy Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba-Geigy Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate as an antioxidant and/or stabilizer in poly(*p*-methylstyrene) and rubber-modified poly(*p*-methylstyrene) intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Bureau of Foods (HHF-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 2B3671) has been filed by Ciba-Geigy Corp., Three Skyline Drive, Hawthorne, NY 10532, proposing that the food additive regulations be amended to provide for the safe use of octadecyl 3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate as an antioxidant and/or stabilizer in poly(*p*-methylstyrene) and rubber-modified poly(*p*-methylstyrene) intended to 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: June 2, 1983.

Richard J. Ronk,

Acting Director for Bureau of Foods.

[FR Doc. 83-16123 Filed 6-16-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 83F-0164]

Calgon Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Food and Drug Administration (FDA) is announcing that the Calgon Corp. has filed a petition proposing that the food additive regulations be amended to provided for the safe use of 2-(4-thiazolyl)benzimidazole as a component of adhesives and paper and paperboard.

FOR FURTHER INFORMATION CONTACT: Geraldine E. Harris, Bureau of Foods (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 2B3627) has been filed by Calgon Corp., Box 1346, Pittsburgh, PA 15230, proposing the § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) be amended to provide for the safe use of 2-(4-thiazolyl)benzimidazole as a component of paper and paperboard for use in food contact applications and that § 175.105 *Adhesives* (21 CFR 175.105) be amended to provide for the safe use of this additive as a component of adhesives.

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: June 9, 1983.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 83-16272 Filed 6-16-83; 8:45 am]

BILLING CODE 4160-01-M

Consumer Participation; Open Meetings

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Food and Drug Administration (FDA) is announcing the following consumer exchange meetings:

Los Angeles District Office, chaired by Abraham I. Kleks, District Director. The topic to be discussed is: Health Fraud.

Date: Monday June 27, 1983, 2:30 p.m.

Address: Parks and Recreation Bldg., 208 Park Ave., San Fernando, CA 91340.

For further information contact: Irene G. Caro, Consumer Affairs Officer, Food and Drug Administration, 1521 West Pico Blvd., Los Angeles, CA 90015, 213-688-4395.

Brooklyn District Office, chaired by George J. Gerstenberg, District Director. The topic to be discussed is: Direct-to-Consumer Advertising of Prescription Drugs.

Date: Wednesday, June 29, 1983, 1:30 p.m.

Address: 26 Federal Plaza, Rm. 305, New York, NY 10278.

For further information contact: Herman B. Janiger, Consumer Affairs Officer, Food and Drug Administration, 850 Third Ave., Brooklyn, NY 11232, 212-965-5754.

Baltimore District Office, chaired by Thomas L. Hooker, District Director. The topic to be discussed is: Direct-to-Consumer Advertising of Prescription Drugs.

Date: Tuesday, July 19, 1983, 10 a.m. to 12 m.

Address: Rosenstock Hall, Hood College, Frederick, MD 21701.

For further information contact: Anne B. Lane, Consumer Affairs Officer, Food and Drug Administration, 900 Madison Ave., Baltimore, MD 21201, 301-962-3731.

Supplementary information: The purpose of these meetings is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's District Offices, and to contribute to the agency's policymaking decisions on vital issues.

Dated: June 10, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-16275 Filed 6-14-83; 11:39 am]

BILLING CODE 4160-01-M

[Docket No. 83C-0051]

Custom Tint Laboratories, Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice

SUMMARY: The Food and Drug Administration (FDA) is announcing that Custom Tint Laboratories, Inc., has filed a petition proposing that the color additive regulations be amended to provide for the safe use of six dyes in coloring contact lenses.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Bureau of Foods (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. 706(b)(1), 74 Stat. 399–402 as amended (21 U.S.C. 376(b)(1))), notice is given that a petition (CAP 3C0169) has been filed by Custom Tint Laboratories, Inc., 6020 Six Forks Rd., Raleigh, NC 27609, proposing that the color additive regulations be amended to provide for the safe use of an orange dye, dibromodibenzo (b,def)chrysene-7,14-dione; a brown dye, 16,23-dihydrodinaphtho(2,3-a:2',3'-i)naphth(2',3':6,7)indolo (2,3-c)-carbazole-5,10,15,17,22,24-hexone; a yellow dye, *N,N'*-(9,10-dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide; an orange dye, 6,6'-diethoxy-2,2'-(3H,3'H) bibenzo(b)thiophene-3,3'-dione; a blue dye, 7,16-dicholoro-6,15-dihydro-5,9,14,18anthrazinetetrone; and a green dye, 16,17-dimethoxydinaphthol(1,2,3-cd:3',2',1'-lm)perylene-5,10-dione in coloring contact lenses.

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: June 9, 1983.

Sanford A. Miller,
Director, Bureau of Foods.

[FR Doc. 83-16274 Filed 6-16-83; 8:45 am]
BILLING CODE 4160-01-M

[Docket No. 83C-0167]

Ethicon, Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ethicon, Inc., has filed a petition proposing to amend the color additive regulations to provide for the safe use of D&C Blue No. 6 to color polydioxanone synthetic absorbable sutures.

FOR FURTHER INFORMATION CONTACT: Blondell Anderson, Bureau of Foods (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. 706(b)(1), 74 Stat. 399–402 as amended (21 U.S.C. 376(b)(1))), notice is given that a petition (CAP 3C0176) has been filed by Ethicon, Inc., Route 22, Somerville, NJ 08876, proposing that Part 74 (21 CFR 74) be amended to provide for the safe use of D&C Blue No. 6 to color polydioxanone synthetic absorbable sutures.

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: June 9, 1983.

Sanford A. Miller,
Director, Bureau of Foods.

[FR Doc. 83-16271 Filed 6-16-83; 8:45 am]
BILLING CODE 4160-01-M

[Docket No. 79D-0465]

Human, Biological, and Animal Drugs and Medical Devices; Availability of Draft Guidelines for Use of the Limulus Amebocyte Lysate (LAL) Test; Extension of Comment Period

AGENCY: Food and Drug Administration.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to July 31, 1983, the comment period for the notice announcing the availability of a draft guideline entitled "Draft Guideline for Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices." The draft guideline sets forth acceptable conditions for use of the Limulus Amebocyte Lysate (LAL) test and describes procedures for using this methodology as an end-product endotoxin test for human injectable drugs (including biological products), animal injectable drugs, and medical devices. FDA is taking this action in response to a request for an extension of the comment period.

DATE: Comments by July 31, 1983.

ADDRESS: Requests for a copy of the draft guideline and written comments regarding the draft guideline to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Human Drugs

Terry E. Munson, National Center for Drugs and Biologics (HFN-325), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6007.

Biological Products

Michael L. Hooton, National Center for Drugs and Biologics (HFN-813), Food and Drug Administration, 8800 Rockville Pike, Bethesda MD 20205, 301–443–1306.

Animal Drugs

Patricia Cushing, Bureau of Veterinary Medicine (HFV-143), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1788.

Medical Devices

Virginia C. Ross, National Center for Devices and Radiological Health (HFK-430), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 29, 1983 (48 FR 13096), FDA issued a notice announcing the availability of a draft guideline entitled "Draft Guideline for Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices." The draft guideline sets forth acceptable conditions for use of the LAL test and describes procedures for using this methodology as an end-product endotoxin test for human injectable drugs (including biological products), animal injectable drugs, and medical devices. The draft guideline is intended to inform interested persons of these acceptable principles which may be used in lieu of the currently official rabbit pyrogen test and was made available for public comment to provide the agency with views to be considered in its development of a final guideline. Interested persons were given to June 27, 1983, to comment on the draft guideline.

In response to the notice, Bayer AG requested an extension of the comment period until July 31, 1983. Bayer AG stated that the **Federal Register** notice announcing the availability of the draft guideline was not available to foreign manufacturers until 5 weeks after publication in the United States and, consequently, the 90-day comment period specified in the notice is unreasonable for foreign manufacturers.

FDA has carefully considered the request. The agency does not accept the argument that the 90-day period

provided in this instance for the submission of comments was insufficient to provide interested persons outside the United States an opportunity to express their views. It is the responsibility of persons having an interest in receiving **Federal Register** announcements in a timely manner to take steps to assure that they receive these announcements soon enough to participate in agency rulemaking matters. However, in this matter, the agency has determined that its schedule for issuing the guideline in final form, as well as the option given firms to start using the LAL test following the procedures set forth in the draft guidelines, permits a general extension of the comment period to July 31, 1983, as requested, and that such an extension to receive pertinent comments is in the public interest. Accordingly, the comment period for submissions by any interested person is extended to July 31, 1983.

Interested persons may, on or before July 31, 1983, submit written comments on the draft guideline to the Docket Management Branch (address above). These comments will be considered in determining whether further amendments to, or revisions of, the draft guideline are warranted. Comments should be in two copies (except that individuals may submit single copies), identified with the docket number found in brackets in the heading of this document. The draft guideline and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Requests for a single copy of the draft guideline should be sent to the Dockets Management Branch.

Dated: June 13, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-16279 Filed 6-14-83; 11:39 am]

BILLING CODE 4160-01-M

[Docket No. 83F-0147]

RohmTech, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that RohmTech, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of pectin glycosidase derived from *Aspergillus alliaceus* for use as a macerase for the manufacture of fruit and vegetable pulp and pulp concentrates.

FOR FURTHER INFORMATION CONTACT: Marvin D. Mack, Bureau of Foods (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 3A3715) has been filed by RohmTech, Inc., 1270 Avenue of the Americas, New York, NY 10020, proposing that 21 CFR Part 173 be amended to provide for the safe use of pectin glycosidase derived from *Aspergillus alliaceus* for use as a macerase for the manufacture of fruit and vegetable pulp and pulp concentrates.

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: June 9, 1983.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 83-16273 Filed 6-16-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 83F-0168]

Witco Chemical Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Witco Chemical Corp. has filed a petition proposing to amend the food additive regulations to provide for the safe use of white mineral oil U.S.P. as a dust suppressant on commodity grain.

FOR FURTHER INFORMATION CONTACT: Blondell Anderson, Bureau of Foods (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 3A3718) has been filed by Witco Chemical Corp., 277 Park Ave., New York, NY 10017, proposing that § 172.878 *White mineral oil* (21 CFR 172.878) be amended to provide for the safe use of white mineral oil U.S.P. as a dust suppressant on commodity grain.

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: June 9, 1983.

Richard J. Ronk,

Acting Director for Bureau of Foods.

[FR Doc. 83-16270 Filed 6-16-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 75N-0248]

Flood Additive Status of Vitamin K Active Substances in Animal Food

Correction

In FR Doc. 83-10171, beginning on page 16748 in the issue of Tuesday, April 19, 1983, the year referred to at the end of the fourth line of the last complete paragraph in column one of page 16749 should read, "1953".

BILLING CODE 1505-01-M

Public Health Service

Ad Hoc Panel on Chemical Carcinogenesis Testing and Evaluation

Notice is hereby given of a meeting of the Ad Hoc Panel on Chemical Carcinogenesis Testing and Evaluation, Subgroup on Data Required From Prechronic Studies, National Toxicology Program (NTP) Board of Scientific Counselors, U.S. Public Health Service, to be held on July 15, 1983, National Institutes of Health, Building 31C, Conference Room 9, Bethesda, Maryland. The meeting will begin at 9:00 a.m. and end at approximately 4:00 p.m. The meeting is open to the public.

The meeting will be held to review the details of the prechronic studies as they are now performed by the NTP, to review the progress of the Panel on the agenda items that were identified at the earlier meeting (May 17, 1983, 48 FR 19476) and to receive comments from interested parties. Items to be discussed include, but not limited to: