Dated: July 16, 1986.

Robert L. Foster,

Acting Director, Office of Program Support, Centers for Disease Control.

[FR Doc. 86-16384 Filed 7-21-86; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[Docket No. 86F-0255]

Buckman Laboratories, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Buckman Laboratories, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of poly[oxyethylene (dimethyliminio) ethylene (dimethyliminio)ethylene dichloride] as an antimicrobial agent in starch in the manufacture of paper and paperboard products for food-contact use.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF-335), 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 5B3835) has been filed by Buckman Laboratories, Inc., 1256 North McLean Blvd., P.O. Box 8305, Memphis, TN 38108, proposing that § 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 poly[oxyethylene (dimethyliminio)ethylene(dimethyliminio) ethylene dichloride] as an antimicrobial agent in starch in the manufacture of paper and paperboard products for food-contact use.

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), as published in the **Federal Register** of April 26, 1985 (50 FR 16636).

Dated: July 11, 1986

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-16364 Filed 7-21-86; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 86F-0280]

Canandaigua Wine Co., Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Canandaigua Wine Co., Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of aspartame as a sweetener in alcoholic beverages containing wine with ethanol content below 7 percent volume per volume.

FOR FURTHER INFORMATION CONTACT: Carl L. Giannetta, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-426-8950.

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 6A3942) has been filed by Canandaigua Wine Co., Inc., 116 Buffalo St., Canandaigua, NY 14424, proposing that § 172.804 *Aspartame* (21 CFR 172.804) be amended to provide for the safe use of aspartame as a sweetener in alcoholic beverages containing wine with ethanol content below 7 percent volume per volume.

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).

Dated: July 11, 1986.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-16368 Filed 7-21-86; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 86F-0281]

Holland American Wafer Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Holland American Wafer Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of aspartame as a sweetener in wafer cookies.

FOR FURTHER INFORMATION CONTACT: Carl L. Giannetta, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-8950.

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 6A3912) has been filed by Holland American Wafer Co., 3300 Roger B. Chaffee Dr. SE., Grand Rapids, MI 49508, proposing that § 172.804 *Aspartame* (21 CFR 172.804) be amended to provide for the safe use of aspartame as a sweetener in wafer cookies.

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), as published in the **Federal Register** of April 26, 1985 (50 FR 16636).

Dated: July 11, 1986.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-16367 Filed 7-21-86; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 86F-0221]

Nebraska Department of Economic Development; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Nebraska Department of Economic Development has filed a petition proposing that the food additive regulation for sucrose fatty acid esters be amended to provide for the safe use of vegetable oils as a source of fatty acids in the manufacture of sucrose fatty acid esters.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Center for Food Safety and Applied Nutrition (HFF-334), Food

and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–5487.

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 5A3859) has been filed on behalf of Nebraska Department of Economic Development, c/o Commonwealth Bldg., 1625 K St. NW., Washington, DC 20006, proposing that § 172.859 *Sucrose fatty acid esters* (21 CFR 172.859) be amended to provide for the safe use of vegetable oils as a source of fatty acids in the manufacture of sucrose fatty acid esters.

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), as published in the **Federal Register** of April 26, 1985 (50 FR 16636).

Dated: July 11, 1986.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86–16365 Filed 7–21–86; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 86F–0274]

Union Carbide Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Union Carbide Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of glutaraldehyde as a slimicide in the manufacture of paper and paperboard that may contact food.

FOR FURTHER INFORMATION CONTACT: Edward J. Machuga, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration 200 C St. SW., Washington, DC 20240, 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 6B3943) has been filed by Union Carbide Corp., Bound Brook, NJ 08805, proposing that § 176.300 *Slimicides* (21 CFR 176.300) be amended to provide for the safe use of glutaraldehyde as a slimicide in the manufacture of paper and paperboard that 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 according with 21 CFR 25.40(c), as published in the **Federal Register** of April 26, 1985 (50 FR 16636).

Dated: July 11, 1986.

Sanford A. Miller,

Director, Center of Food Safety and Applied Nutrition.

[FR Doc. 86–16369 Filed 7–21–86; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 83F–0263]

Westvaco; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal without prejudice of a petition (FAP 3B3728) proposing that the food additive regulations be amended to provide for the safe use of mono-, di-, or tri-(1-phenylethyl)phenol, ethoxylated, sulfosuccinated, sodium salt as an emulsifier in the manufacture of paper and paperboard.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 19, 1983 (48 FR 37714), FDA published a notice that it had filed a petition (FAP 3B3728) from Westvaco Corp., P.O. Box 70848, Charleston Heights, SC 29405, that proposed to amend § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) of the food additive regulations to provide for the safe use of mono-, di-, tri-(1-phenylethyl)phenol, ethoxylated, sulfosuccinated, sodium salt as an emulsifer in the manufacture of paper and paperboard. Westvaco Corp. has not withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: July 11, 1986.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86–16366 Filed 7–21–86; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 84P–0281]

Canned Green Beans Deviating From Identity Standard; Further Amendment of Temporary Permit for Market Testing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit issued to the Friday Canning Corp., and Continental Can Co., Inc., to market test experimental packs of canned green beans containing added zinc chloride is being further amended to reflect that the test product is to be manufactured at one additional plant.

DATE: The expiration date of the permit will be either the effective date of a final rule for any proposal to amend the standard of identity for canned green beans which may result from the petition, or 30 days after termination of such rulemaking.

FOR FURTHER INFORMATION CONTACT: Catharine R. Calvert, Center for Food Safety and Applied Nutrition (HFF–214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–485–0121.

SUPPLEMENTARY INFORMATION: A temporary permit was issued under the provisions of 21 CFR 130.17 to the Friday Canning Corp., 150 West First St., P.O. Box 129, New Richmond, WI 54017, and Continental Can Co., Inc., 800 Connecticut Ave., P.O. Box 5410, Norwalk, CT 06856 (formerly 51 Harbor Plaza, Box Number 10004, Stamford, CT 06904–2004), to market test canned green beans containing added zinc chloride to retain the color of the test product (up to 75 parts per million of zinc in the finished food). The permit was issued in order to facilitate market testing of foods that deviate from the requirements of the standards of identify promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). Notice of issuance of the temporary permit to the Friday Canning Corp., and Continental Can Co., Inc., was published in the **Federal Register** of September 20, 1984 (49 FR 36925).

Continental Can Co., Inc., jointly with other sponsors, submitted a petition to amend 21 CFR 155.120 to provide for the

use of zinc chloride for stabilization of color. At the same time, the Friday Canning Corp., and Continental Can Co., Inc., jointly submitted a request to extend and amend their temporary permit to increase the number of cases of test product for the marketing test. A notice of an extension and amendment of the temporary permit to increase the number of cases of test product was published in the **Federal Register** of March 13, 1986 (51 FR 8709).

Continental Can Co., Inc., on behalf of the Friday Canning Corp., has requested that the temporary permit be amended to permit the test product to be manufactured at an additional plant. Accordingly, FDA, under the provisions of 21 CFR 130.17(f), is further amending the temporary permit to indicate that, in addition to the plant located at Cambria, WI 53923, the test product is to be manufactured at the Friday Canning Corp. plant located at Gillett, WI 54124.

All other conditions and terms of this permit remain the same. The expiration date of the permit will be either the effective date of a final rule for any proposal to amend the standard of identity for canned green beans which may result from the petition, or 30 days after termination of such rulemaking.

Dated: July 10, 1986

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-16370 Filed 7-21-86; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 86M-0270]

Ethicon, Inc.; Premarket Approval of PDS™ (Polydioxanone), Dyed and Clear Monofilament Synthetic Absorbable Sutures

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of a supplemental application by Ethicon, Inc., Somerville, NJ, for premarket approval, under the Medical Device Amendments of 1976, of the PDS™ (polydioxanone) Dyed and Clear Monofilament Synthetic Absorbable Sutures. After reviewing the recommendation of the General and Plastic Surgery Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant of the approval of the supplemental application.

DATE: Petitions for administrative review by August 21, 1986.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kenneth A. Palmer, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION: On March 8, 1985, Ethicon, Inc., Somerville, NJ 08876, submitted to CDRH a supplemental application for premarket approval of the PDS™ (polydioxanone) Dyed and Clear Monofilament Synthetic Absorbable Sutures for an additional indicated use for these previously approved devices (46 FR 59311; December 4, 1981). Ethicon, Inc., requested approval for use of the devices in pediatric cardiovascular tissue where growth is expected to occur.

PDS™ sutures are available as sterile, monofilament dyed (violet) strands in sizes 9-0 to 2 (metric size 0.3 to 5), and as sterile, monofilament dyed (blue) strands in sizes 10-0 to 7-0 (metric size 0.2 to 0.5) in a variety of lengths with a variety of needles. Sterile monofilament dyed (violet) sutures, sizes 4-0 to 1 (metric size 1.5 to 4) are also available attached to control release removable needles. Sterile, monofilament, clear suture strands are available in sizes 7-0 to 1 (metric size 0.5 to 4) in a variety of lengths with permanently attached needles.

On March 25, 1985, the General and Plastic Surgery Devices Panel, an FDA advisory committee, reviewed and recommended approval of the supplemental application. On June 6, 1986, CDRH approved the supplemental application by a letter to the applicant from the Director of the Office of Device Evaluation, CDHR. With FDA's approval of the supplemental application, the indicated uses of these devices read as follows: PDS ™ (polydioxanone) Dyed and Clear Monofilament Synthetic Absorbable Sutures are indicated for use in all types of soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery. PDS ™ suture is not indicated in adult cardiovascular tissue, microsurgery, and neural tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to 6 weeks) is desirable.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact Kenneth A. Palmer (HFZ-410), address above.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g), for administrative review of CDRH's decision to approve this supplemental application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register.** If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 21, 1986, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), 90 Stat. 554-555, 571 (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).