DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0301]

Ube Industries (America), Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ube Industries (America), Inc., has filed a petition proposing that the food additive regulations be amended to change the melting point range specifications for Nylon 6/66 resins intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

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 7B4548) has been filed by Ube Industries (America), Inc., c/o Center for Regulatory Services, 2347 Paddock Lane, Reston, VA 20191. The petition proposes to amend the food additive regulations in § 177.1500 *Nylon resins* (21 CFR 177.1500), for Nylon 6/66 resins described in the table in paragraph (b), item 4.2, to change the melting point range from 380–400 °F to 380–425 °F.

The agency has determined under 21 CFR 25.24(9) that this action is of the 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: July 8, 1997.

Laura M. Tarantino,

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

[FR Doc. 97–19127 Filed 7–18–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92G–0432]

Yandilla Mustard Oil Enterprise Pty. Ltd.; Withdrawal of GRAS Affirmation Petition

AGENCY: Food and Drug Administration., HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (GRASP 0G0359) proposing that low erucic acid mustard seed oil be affirmed as generally recognized as safe (GRAS) as a direct human food ingredient.

FOR FURTHER INFORMATION CONTACT: Nega Beru, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3097.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 22, 1993 (58 FR 5736), FDA announced that a petition had been filed by Yandilla Mustard Oil Enterprise Pty. Ltd., Wallendbeen, NSW 2588, Australia. This petition proposed that low erucic acid mustard seed oil be affirmed as GRAS for use as a direct human food ingredient.

In response to repeated requests from the petitioner urging action, on October 4, 1994, the agency informed the petitioner that a decision on whether the agency concurs with the petitioner's determination that Yandilla mustard seed oil is GRAS is not likely to be forthcoming for some time. The agency cited resource constraints and the work that still needed to be done in order to resolve certain safety issues raised by the petition. No response was received from the petitioner.

By letter dated April 4, 1996, FDA reiterated to the petitioner why the agency is unlikely to reach a decision on the petition in the near future and further informed the petitioner of an agency initiative to remove from its pending petition inventory those petitions on which the agency is unable to reach closure in the near future. In that letter, the agency requested that the petitioner withdraw the petition, without prejudice to a future filing, and asked the petitioner to inform the agency of its decision within 30 days of the date of the letter; the agency added that failure to respond within that time would be considered tacit approval to withdraw the petition. More than 1 year has passed since the letter was sent and the firm has not responded. Indeed, the last communication from the petitioner was in June 1994. Therefore, the agency is announcing that it considers this petition to be withdrawn by the firm, without prejudice to a future filing.

Dated: July 2, 1997.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–19123 Filed 7–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 87N–0262]

Merck & Co., Inc., et al.; Withdrawal of Approval of 39 New Drug Applications, 13 Abbreviated Antibiotic Applications, and 46 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 25, 1997 (62 FR 34297). The document announced the withdrawal of approval of 39 new drug applications (NDA's), 13 abbreviated antibiotic applications (AADA's), and 46 abbreviated new drug applications (ANDA's). The document inadvertently withdrew approval of NDA 50–678 for DYNABAC (dirithromycin tablets) held by Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, IN 46285. This document confirms that approval of NDA 50–678 is still in effect, and that the withdrawal of approval of the NDA was in error.

EFFECTIVE DATE: June 25, 1997.

FOR FURTHER INFORMATION CONTACT: Olivia A. Vieira, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–594–2041.

In FR Doc. 97–16609 appearing on page 34297 in the issue of Wednesday, June 25, 1997, the following correction is made: On page 34298, in the table, the entry for NDA 50–678 is removed.

Dated: July 11, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–19012 Filed 7–18–97; 8:45 am]

BILLING CODE 4160–01–F