

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 97F-0388]

Cultor Food Science, Inc.; Filing of Food Additive Petition**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Cultor Food Science, Inc., has filed a petition proposing that the food additive regulations be amended to permit aqueous transition metal catalytic hydrogenation in the production of polydextrose and to adopt the specifications for polydextrose of the Food Chemicals Codex, 4th ed., 1996.

DATES: Written comments on the petitioner's environmental assessment by October 27, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rosalie M. Angeles, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3107.

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 7A4556) has been filed by Cultor Food Science, Inc., 205 East 42d St., New York, NY 10017. The petition proposes to amend the food additive regulations in § 172.841 *Polydextrose* (21 CFR 172.841) to permit aqueous transition metal catalytic hydrogenation in the production of polydextrose and to adopt the specifications for polydextrose of the Food Chemicals Codex, 4th ed., 1996, pp. 297-300.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before October 27, 1997 submit to the Dockets Management Branch (address above) written

comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, 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: September 9, 1997.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.
[FR Doc. 97-25368 Filed 9-24-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food And Drug Administration**

[Docket No. 97F-0405]

Shikoku Chemical Corp.; Filing of Food Additive Petition**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Shikoku Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of aluminum borate as an antistatic agent and/or antifogging agent for olefin polymers intended for use as packaging materials 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 7B4559) has been filed by Shikoku Chemical Corp., c/o SRS International Corp., suite 1000, 1625 K St. NW., Washington DC 20006-1604. The petition proposes to amend the food

additive regulations in § 178.3130 Antistatic and/or antifogging agents in food-packaging materials (21 CFR 178.3130) to provide for the safe use of aluminum borate as an antistatic and/or antifogging agent for olefin polymers complying with 21 CFR 177.1520(c) as packaging materials intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) 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: September 11, 1997.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.
[FR Doc. 97-25430 Filed 9-24-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 97N-0399]

Helen A. Ballack Co. et al.; Withdrawal of Approval of 61 New Drug Applications, 8 Abbreviated Antibiotic Applications, and 36 Abbreviated New Drug Applications**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 61 new drug applications (NDA's), 8 abbreviated antibiotic applications (AADA's), and 36 abbreviated new drug applications (ANDA's). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: September 25, 1997.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also,