perfluoroC_{4-20}alkylthio)methyl]-1,3-propanediol, polyphosphoric acid (CAS Reg. No. 8017–16–1) and ammonium hydroxide as an oil and water repellant for paper and paperboard intended for use in contact with food.

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 display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before August 19, 1996, 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: June 27, 1996.

Alan M. Rulis,

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

[FR Doc. 96–18165 Filed 7–17–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96F–0213]

Toyobo Co., Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Toyobo Co., Ltd., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 1,4-benzenedicarboxylic acid, polymer with 1,4-butanediol, (Σ)-2-butanedioic acid, 1,2-ethanediol, ethyl-2-propenoate, hexanedioic acid and 2-propenoic acid, graft, in nylon 6 and nylon 6 modified with nylon MXD–6 articles intended for use in contact with food.

DATES: Written comments on petitioner's environmental assessment by August 19, 1996.

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: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), 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 6B4511) has been filed by Toyobo Co., Ltd., 2–1–1 Hon Katata Otsu, Shiga 520–02, Japan. The petition proposes to amend the food additive regulations to provide for the safe use of 1,4-benzenedicarboxylic acid, polymer with 1,4-butanediol, (Σ)-2-butanedioic acid, 1,2-ethanediol, ethyl 2-propenoate, hexanedioic acid and 2-propenoic acid, graft, in nylon 6 and nylon 6 modified with nylon MXD–6 articles intended for use in contact with food. The graft resins of this type are generically called copolyester-graft-copolymer.

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 display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before August 19, 1996, 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: June 20, 1996.

George H. Pauli,

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

[FR Doc. 96–18284 Filed 7–17–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0220]

Healthdyne, Inc.; Premarket Approval of System 37® Home Uterine Activity Monitoring System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Healthdyne, Inc., Marietta, GA 30067, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of System 37® Home Uterine Activity Monitoring System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on September 29, 1995, of the approval of the application.

DATES: Petitions for administrative review by August 19, 1996.

ADDRESSES: 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, 12420 Parklawn Drive, rm. 1–23,Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION: On July 24, 1992, Healthdyne, Inc., Marietta, GA 30067, submitted to CDRH an application for premarket approval of System 37® Home Uterine Activity Monitoring System. The device is a Home Uterine Activity Monitor and is indicated for use, in conjunction with standard high risk care, for the daily at-home measurement of uterine activity in pregnancies ≥ 24 weeks gestation for women with previous preterm delivery. Uterine activity data are displayed at a remote location to aid in the early detection of preterm labor.