

Respondents	No. of respondents	No. of responses/responses	Avg. burden/response (in hours)
Child care provider	70	1	0.5

The total annual burden is 693. Send comments to the CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503.

2. National Survey of Ambulatory Surgery—(0920–0334)—Extension—The National Survey of Ambulatory Surgery (NSAS) has been conducted annually since 1994 by the National Center for Health Statistics, CDC. It is the only source of clinical information nationally on utilization of ambulatory surgery. It complements surgery data obtained in another NCHS survey, the National Hospital Discharge Survey (NHDS), which provides annual data concerning the nation's use of inpatient medical and surgical care provided in short-stay, non-Federal hospitals. These NHDS data have been used for more than two decades to analyze the types of surgical treatment provided to hospital

inpatients. However, due to advances in medical technology, many surgical treatments and diagnostic procedures are now provided in ambulatory settings which are outside the scope of the NHDS. The NSAS, a national probability sample of hospital-based and freestanding ambulatory surgery centers in the U.S., has been designed to provide valid data about medical and surgical care received in ambulatory surgery locations. Data for the NSAS are collected annually on approximately 120,000 ambulatory surgery cases. The data items which are abstracted from medical records are the basic core of variables from the Uniform Hospital Discharge Data Set (UHDDS) as well as surgery times, total charges and information on anesthesia. These NSAS data will be used for a variety of planning, administrative, and

evaluation activities by government, professional, scientific, academic, and commercial institutions. Data collected through the NSAS are essential for evaluating health status of the population, for the planning of programs and policy to elevate the health status of the Nation, for studying morbidity trends, and for research activities in the health field. For example, selected government agencies are interested in specific NSAS data to track the incidence of selected ambulatory procedures, e.g., estimates of tubal sterilization, estimates of endoscopies and related digestive tract procedures, and estimates of endoscopic removal of pre-cancerous polyps. In addition, NSAS data will provide annual updates for numerous tables in the Congressionally-mandated NCHS report, Health, United States.

Respondents	No. of responses	No. of responses/respondent	Avg. burden/response (in hrs.)
Induction	40	1	1.5
Out-of-scope Verification	140	1	0.066
Sample Listing Sheet:			
ASC Personnel	224	12	0.5
Census Personnel	267	12	0
Medical Abstract:			
ASC Personnel	324	250	0.2
Census Personnel	167	250	0.03333
Annual Update	491	1	0.083
Quality Control	245	20	0.0333

The total annual burden is 19,209. Send comments to the CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503.

Dated: July 12, 1996.

Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–18237 Filed 7–17–96; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 96F–0242]

Ciba-Geigy Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

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 perfluoroalkyl substituted phosphate ester acids, ammonium salts, formed by the reaction of 2,2-bis[(γ,ω-perfluoroC₄₋₂₀alkylthio)methyl]-1,3-propanediol, polyphosphoric acid and ammonium hydroxide as an oil and water repellant for paper and paperboard 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 6B4513) has been filed by Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419–8300. The petition proposes to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of perfluoroalkyl substituted phosphate ester acids, ammonium salts, formed by the reaction of 2,2-bis[(γ,ω-

perfluoroC₄₋₂₀alkylthio)methyl]-1,3-propanediol, polyphosphoric acid (CAS Reg. No. 8017-16-1) and ammonium hydroxide as an oil and water repellent 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.