acquired HIV before moving to their current residence, and (7) describe and compare the extent of and reasons for this migration in HIV-infected persons currently living in small cities and rural areas of the South. The total cost to respondents is estimated at $7,000.

Respondents	No. of respondents	No. of responses/respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
HIV-infected adults receiving HIV care	700	.....	1	700
Total	.....	.....	.....	700

Dated: March 19, 1996.

Wilma G. Johnson,

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

[FR Doc. 96–7137 Filed 3–22–96; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 96F–0092]

Asahi Denka Kogyo K.K.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Asahi Denka Kogyo K.K. has filed a petition proposing that the food additive regulations be amended to provide for the expanded safe use of phosphorous acid, cyclic neopentanetetrayl bis(2,6-di-*tert*-butyl-4-methylphenyl)ester as an antioxidant and/or stabilizer at a level not to exceed 0.05 percent by weight in olefin copolymers intended for use in contact with food.

DATES: Written comments on petitioner's environmental assessment by April 24, 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 6B4498) has been filed by Asahi Denka Kogyo K.K., 2–13 Shirahata 5–Chome, Urawa City, Saitama 336, Japan. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers in polymers* (21 CFR 178.2010) to expand the safe use of phosphorous acid, cyclic neopentanetetrayl bis(2,6-di-*tert*-butyl-4-methylphenyl)ester for use as an antioxidant and/or stabilizer at levels not to exceed 0.05 percent by weight of olefin polymers complying with 21 CFR 177.1520 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 April 24, 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: March 7, 1996.

Alan M. Rulis,

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

[FR Doc. 96–7105 Filed 3–22–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96D–0065]

''Medical Device Design Control Guidance'' and ''Do It By Design;'' Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two draft guidance documents entitled, ''Medical Device Design Control Guidance'' and ''Do It By Design.'' The ''Medical Device Design Control Guidance'' draft document is intended to provide a general understanding of design control theory, principles, and methods, and to update a previous guidance document on the subject of preproduction quality assurance. The ''Do It By Design'' draft guidance document is intended to provide a general understanding of the human factors theory as it relates to designing a medical device. Both draft guidance documents, once finalized, are intended to be basic educational tools for industry and FDA field investigators, and they will be used to aid implementation of the new ''quality system regulation,'' now in the final stages of development.

DATES: Written comments by April 30, 1996.

ADDRESSES: Submit written requests for single copies of the draft guidances to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist the office in processing your request. Copies of a facsimile of the draft guidances are available from CDRH Facts on Demand (1–800–899–0381). Copies of the draft guidances may also be obtained from the Electronic Docket administered by DSMA and are available to anyone with a video terminal or personal computer (1–800–252–1366).

Submit written comments to the Dockets Management Branch (HFA–

305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments for the two draft guidance documents should be kept separate and identified by their respective titles. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidances and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Kimberly A. Trautman, Office of Compliance, Center for Devices and Radiological Health (HFZ–341), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4648.

SUPPLEMENTARY INFORMATION:

I. Background

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), enacted on November 28, 1990, amended section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j (f)), providing FDA with the authority to add preproduction design controls to the current good manufacturing practice (CGMP) regulation part 820 (21 CFR part 820). This change in law was based on findings that a significant proportion of device recalls were attributed to faulty product design. FDA found that approximately 44 percent of the quality problems that led to voluntary recall actions during a 6-year period were attributed to errors or deficiencies that had been designed into particular devices and that may have been prevented by adequate design controls. These design-related defects involved both noncritical devices (e.g., patient chair lifts, in vitro diagnostics, and administration sets) and critical devices (e.g., pacemakers and ventilators). Also in 1990, the Department of Health and Human Services' Inspector General conducted a study which reached similar conclusions.

FDA undertook the revision of the CGMP regulation to add the design controls authorized by the SMDA to the CGMP regulation and because the agency believed that it would be beneficial to the public and the medical device industry for the CGMP regulation to be consistent, to the extent possible, with the requirements for quality systems contained in international standards. The agency's extensive efforts to revise the CGMP regulation included making publicly available a working draft of a final rule in July 1995, followed by a public workshop on August 23, 1995 (see 60 FR 37856, July 24, 1995), and an open public GMP Advisory Committee meeting on September 13 and 14, 1995 (see 60 FR 44037, August 24, 1995). The final regulation, generally referred to as the quality system regulation, is now in the final stages of development.

The ''Medical Device Design Control Guidance'' and ''Do It By Design'' draft guidance documents are intended to provide assistance in understanding what design controls are and provide recommendations on how to establish design controls, which would be consistent with the new design control requirements. The draft guidance ''Medical Device Design Control Guidance'' updates the Center for Devices and Radiological Health's ''Preproduction Quality Assurance Planning: Recommendations for Medical Device Manufacturers,'' announced as a final document in the Federal Register of October 5, 1989 (54 FR 41165). The draft guidance documents are projected to be finalized later this year, soon after the new quality system regulation is published.

II. Significance of a Guidance

A guidance document does not bind FDA or the public, and does not create or confer any rights, privileges, or benefits for or on any person; however, it does represent the agency's current thinking on the subjects discussed therein. The draft guidance documents announced in this notice represent the agency's tentative thinking on design controls and the relationship of human factors with design controls.

III. Request for Comments

Interested persons may, on or before April 30, 1996, submit to the Dockets Management Branch (address above) written comments regarding the draft guidances. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified by the title of the respective draft guidance and with the docket number found in brackets in the heading of this document. The two draft guidance documents and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in revising the draft guidance documents.

Dated: March 15, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–7047 Filed 3–22–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Special Project Grants and Cooperative Agreements; Maternal and Child Health Services; Federal Set-Aside Program; Comprehensive Hemophilia Centers, Genetic Services, and Maternal and Child Health Improvement Projects

AGENCY: Health Resources and Services Administration (HRSA), PHS.

ACTION: Notice of availability of funds.

SUMMARY: The HRSA announces that applications will be accepted for fiscal year (FY) 1996 funds for grants and cooperative agreements for the following activities: Maternal and Child Health (MCH) Special Projects of Regional and National Significance (SPRANS), including comprehensive hemophilia diagnostic and treatment centers; genetic disease testing, counseling and information services; and special MCH improvement projects (MCHIP) which contribute to the health of mothers, children, and children with special health care needs (CSHCN). All awards will be made under the program authority of section 502(a) of the Social Security Act, the MCH Federal Set-Aside Program. A revised regulation implementing the Federal Set-Aside Program (42 CFR part 51a) was published in the July 19, 1994, issue of the Federal Register at 59 FR 36703. Within the HRSA, SPRANS grants are administered by the Maternal and Child Health Bureau (MCHB). Awards are made for grant periods which generally run from 1 up to 5 years in duration. Grants for SPRANS research and training are being announced in a separate notice.

This program announcement is subject to the appropriation of funds. Applicants are advised that this program announcement is a contingency action being taken to assure that should funds become available for this purpose, they can be awarded in a timely fashion consistent with the needs of the program as well as to provide for even distribution of funds throughout the fiscal year. At this time, given a continuing resolution and the absence of FY 1996 appropriations for the MCH Federal Set-Aside Program, the amount