

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 neopentetetrayl 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 neopentetetrayl 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-