Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: June 17, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–16627 Filed 6–22–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0436]

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 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)2-ethylhexyl phosphite as an antioxidant and/or stabilizer in high density polyethylene articles intended for contact with food.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–15), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3095.

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 8B4599) has been filed by Asahi Denka Kogyo K.K., c/o Japan Technical Information Center, Inc., 775 S. 23d St., Arlington, VA 22202. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the expanded safe use of 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)2-ethylhexyl phosphite as an antioxidant and/or stabilizer in high density polyethylene articles intended for 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: June 11, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–16622 Filed 6–22–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 77N–0240]

Erythrityl Tetranitrate; Drug Efficacy Study Implementation; Revocation of Exemption; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revoking the temporary exemption that has allowed single-entity coronary vasodilator drug products containing erythrityl tetranitrate to remain on the market beyond the time limits scheduled for implementation of the Drug Efficacy Study. FDA is announcing that the products lack substantial evidence of effectiveness and is offering an opportunity for a hearing on a proposal to withdraw approval of any applicable new drug applications (NDA's) or abbreviated new drug applications (ANDA's).

DATES: The revocation of exemption is effective June 23, 1998; requests for hearings are due on or before July 23, 1998; data in support of hearing requests are due on or before August 24, 1998.

ADDRESSES: Communications in response to this notice should be identified with the reference number DESI 1786 and directed to the attention of the appropriate office named below.

A request for a hearing, supporting data, and other comments are to be identified with Docket No. 77N–0240 and submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

A request for an opinion on applicability of this notice to a specific product should be directed to the Division of Prescription Drug Compliance and Surveillance (HFD–330), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

Under the agency's Drug Efficacy Study Implementation (DESI) program, the National Academy of Sciences/National Research Council (NAS/NRC) evaluated the effectiveness of certain coronary vasodilators. Based on NAS/NRC's recommendations, FDA classified the coronary vasodilators as probably and possibly effective for indications relating to the management, prophylaxis, or treatment of anginal attacks. This classification was announced in the **Federal Register** of February 25, 1972 (37 FR 4001).

In a notice published in the **Federal Register** of December 14, 1972 (37 FR 26623), as amended July 11, 1973 (38 FR 18477), August 26, 1977 (42 FR 43127), October 21, 1977 (42 FR 56156), and September 15, 1978 (43 FR 41282), FDA temporarily exempted the single-entity coronary vasodilators covered by the DESI program from the time limits established for completing the program (Paragraph XIV, Category I exemption). FDA granted this exemption to allow manufacturers additional time to conduct clinical studies to determine effectiveness of the drugs for prevention of anginal attacks. In the August 26, 1977, notice, FDA added certain dosage forms of erythrityl tetranitrate (not included in the Drug Efficacy Study but regarded as related drugs) to the Paragraph XIV, Category I exemption.

The exemption notices established conditions for marketing the single-entity coronary vasodilators pending FDA's conclusions about the products. FDA required that each manufacturer conduct bioavailability studies on its own product(s) and that at least one manufacturer conduct clinical effectiveness studies for each chemical entity to which the same effectiveness conclusions would ultimately apply. An