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

ANDA was required for marketing of products not the subject of an NDA; such products were to be conditionally approved, pending the results of ongoing studies. Conditionally approved ANDA's were given the same status as the ''deemed approved'' NDA's under review in the DESI program, i.e., safe but not proven effective (42 FR 43127 and 43129).

The following applications for erythrityl tetranitrate received conditional approval under the terms of the exemption notices:

1. ANDA 86–194; Cardilate Chewable Tablets containing 10 milligrams (mg) erythrityl tetranitrate per tablet; Glaxo Wellcome (formerly Burroughs Wellcome), 3030 Cornwallis Rd., P.O. Box 12700, Research Triangle Park, NC 27709–2700.

2. ANDA 86–203; Cardilate Tablets containing 5, 10, or 15 mg of erythrityl tetranitrate per tablet; Glaxo Wellcome.

In response to the exemption notices, the then Burroughs Wellcome Co. submitted efficacy data on its erythrityl tetranitrate products, but later requested in separate letters that FDA withdraw approval of ANDA's 86–194 and 86–203, stating that the marketing of the products had been discontinued. FDA withdrew approval of ANDA 86–194 in the **Federal Register** of February 13, 1996 (61 FR 5562 at 5563). FDA considers the requests for withdrawal of the ANDA's to also constitute requests for withdrawal of the efficacy data. Accordingly, FDA is now proposing to withdraw approval of the applications based on lack of substantial evidence of effectiveness.

II. Revocation of Exemption

According to FDA's records, no person other than Glaxo Wellcome has submitted data or expressed an intention to perform clinical studies on single-entity erythrityl tetranitrate, and it is now reclassified to lacking substantial evidence of effectiveness. The temporary exemption, as it pertains to the drug, is revoked.

No other single-entity coronary vasodilators remain exempt under the Paragraph XIV, Category I exemption, and Category I is now dissolved.

III. Notice of Opportunity for a Hearing

On the basis of all the data and information available to her, the Director of the Center for Drug Evaluation and Research is unaware of any adequate and well-controlled clinical investigation, conducted by experts who are qualified by scientific training and experience, meeting the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (the act)(21 U.S.C. 355) and 21 CFR 314.126, that demonstrates effectiveness of single-entity erythrityl tetranitrate.

Notice is given to the holder of any NDA or ANDA for single-entity erythrityl tetranitrate, to manufacturers or distributors of the drug, and to all other interested persons, that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the act withdrawing approval of any NDA or ANDA and all amendments and supplements thereto providing for single-entity erythrityl tetranitrate and its indication relating to the management, prophylaxis, or treatment of anginal attacks. The Director of the Center for Drug Evaluation and Research finds that new information before her with respect to the drug, evaluated together with the evidence available to her when applications were approved under the exempting notices, shows that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

This notice applies to any person who manufactures or distributes a drug product containing single-entity erythrityl tetranitrate that is not the subject of an approved NDA and that is identical, related, or similar as defined in § 310.6 (21 CFR 310.6). It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product that the person manufactures or distributes. Any person may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Prescription Drug Compliance and Surveillance (address above).

This notice of opportunity for a hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in § 310.6), e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act (21 U.S.C. 321(p)) or because it is exempt from part or all of the new drug provisions of the act under the exemption for products marketed before June 25, 1938, in section 201(p) of the act, or under section 107(c) of the Drug Amendments of 1962 (Pub. L. 87–781), or for any other reason.

In accordance with section 505 of the act and the regulations issued under it (21 CFR parts 310 and 314), an applicant and all other persons subject to this notice are hereby given a opportunity for a hearing to show why approval of any applicable NDA's or ANDA's should not be withdrawn.

An applicant or any other person subject to this notice who decides to seek a hearing shall file: (1) On or before July 23, 1998, a written notice of appearance and request for a hearing, and (2) on or before August 24, 1998, the data, information, and analyses relied on to demonstrate that there is a genuine issue of material fact to justify a hearing, as specified in § 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in §§ 314.150 and 314.200, and in 21 CFR part 12.

The failure of an applicant or any other person subject to this notice to file a timely written notice of appearance and request for a hearing, as required by § 314.200, constitutes an election by that person not to use the opportunity for a hearing concerning the action proposed and a waiver of any contentions concerning the legal status of that person's drug product(s). Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for a hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for a hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions pursuant to this notice of opportunity for a hearing are to be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director of the

Center for Drug Evaluation and Research (21 CFR 5.70 and 5.82).

Dated: May 28, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98–16578 Filed 6–22–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Statement of Organization, Functions, and Delegations of Authority

Part F, of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services, Health Care Financing Administration (HCFA), 49 FR 34247, dated September 6, 1984, is amended to include the following delegation of authority from the Secretary to the Administrator, HCFA, for carrying out Title XXVII, of the Public Health Service Act, as amended.

- Section F.30., Delegations of Authority is amended by adding the following paragraph.

UU. The authority vested in the Secretary by Title XXVII of the Public Health Service Act, as amended by the Health Insurance Portability and Accountability Act of 1986, Public Law 104–191.

This delegation shall be exercised under the Department's policy on regulations. In addition, I hereby affirm and ratify any actions taken by the Administrator or other HCFA officials which, in effect, involved the exercise of this authority prior to the effective date of this delegation.

This delegation is effective immediately.

Dated: June 11, 1998.

Donna E. Shalala,

Secretary.

[FR Doc. 98–16592 Filed 6–22–98; 8:45 am]

BILLING CODE 4120–07–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Biologic Specimen-Based Study of Dietary Measurement Error for Nutritional Epidemiology and Surveillance

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Biologic specimen-based study of dietary measurement error for nutritional epidemiology and surveillance. *Type of Information Collection Request:* New. *Need and use of Information Collection:* The agency conducts and funds studies examining the relationship between diet and chronic diseases. The study will collect, on a sample of 400 free-living men and women, 40–69 years of age, two 24-hour dietary recalls, two food frequency questionnaires, a physical activity questionnaire, a dietary screener questionnaire, and an opinion form. Respondents will receive a dose of doubly labeled water and provide spot urine samples to measure energy expenditure, will collect two 24-hour urines to measure urinary nitrogen, and provide blood samples to measure biochemical measures of dietary intake. The data will be used to assess the magnitude and structure of dietary measurement error in dietary surveillance and nutritional epidemiologic studies. *Frequency of response:* One-time study. *Affected public:* Individuals or households. *Types of Respondents:* U.S. adults 40–69 years of age. The annual reporting burden is as follows:

Data collection	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total hour burden	Estimated total annual burden hours requested
Screener	400	1	0.167	67	67
24-hour recall #1	400	1	.5	200	200
24-hour recall #2	400	1	.5	200	200
Food frequency questionnaire #1	400	1	1	400	400
Food frequency questionnaire #2	400	1	1	400	400
Physical activity questionnaire	400	1	.25	100	100
Opinion forms	400	1	.25	100	100
Dietry screener questionnaire	400	1	.167	67	67
Dosing with DLW/initial urine collections	400	1	4	1600	1600
Spot urine collections	400	1	0.25	100	100
Spot hr urine collection #1	400	1	.167	67	67
24-hr urine collection #2	400	1	.167	67	67
Blood collection	400	1	.25	100	100
Total	400	1	.67	3,468	3,468

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proposed performance of the functions of the agency, including whether the information shall have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.