petitioner is required to include in the petition.

FDA estimates the burden resulting from the requirements of § 101.12(h) as follows:

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating & Maintenance Costs
101.12(h)	5	1	5	80	400	$400,000

There are no capital costs associated with this collection.

Since the enactment of the 1990 amendments that revised the act by adding section 403(q), FDA has received nine petitions to amend existing reference amounts. Based upon these submissions, FDA estimates that no more than five such petitions will be submitted annually. The estimate for operating and maintenance costs is based on the average cost of conducting a consumer survey to support a reference amount petition.

Dated: May 22, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–13536 Filed 5–29–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96F–0164]

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 safe use of sodium 2,2'-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in high density polyethylene intended for use in contact with food.

DATES: Written comments on the petitioner's environmental assessment by July 1, 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 6B4504) 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 § 178.3295 *Clarifying agents for polymers* (21 CFR 178.3295) to provide for the safe use of sodium 2,2'-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in high density polyethylene 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 July 1, 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: May 14, 1996.

George H. Pauli,

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

[FR Doc. 96–13464 Filed 5–29–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95E–0385]

Determination of Regulatory Review Period for Purposes of Patent Extension; PRECOSE™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PRECOSE™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis

for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product PRECOSE™ (acarbose). PRECOSE™ is indicated as an adjunct to diet to lower blood glucose in patients with noninsulin-dependent diabetes mellitus who hyperglycemia cannot be managed by diet alone. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PRECOSE™ (U.S. Patent No. 4,904,769) from Bayer AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 27, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period that the approval of PRECOSE™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for PRECOSE™ is 5,647 days. Of this time, 3,789 days occurred during the testing phase of the regulatory review period, while 1,858 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: March 23, 1980. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on March 23, 1980.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: August 6, 1990. The applicant claims August 9, 1990, as the date the new drug application (NDA) for PRECOSE™ (NDA 20–086) was initially submitted. However, FDA records indicate that NDA 20–086 for the active ingredient in PRECOSE™ (acarbose) was received by the agency on August 6, 1990. This NDA was withdrawn on August 28, 1991. A subsequent NDA for PRECOSE™ (NDA 20–482) was received on September 6, 1994. Therefore, NDA 20–086 signifies the end of the testing phase and the beginning of the approval phase for PRECOSE™, while NDA 20–482 signifies the end of the approval phase. The NDA initially submitted date is August 6, 1990.

3. *The date the application was approved*: September 6, 1995. FDA verified the applicant's claim that NDA 20–482 was approved on September 6, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 922 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 29, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 26, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 16, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–13535 Filed 5–29–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–2552–96]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Hospital and Hospital Health Care Complex Cost Report; *Form No.:* HCFA–2552–96; *Use:* This form is required by statute and regulation for participation in the Medicare program. The information is used to determine final payment for Medicare. Hospitals and related complexes are the main users. *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 7,000; *Total Annual Responses:* 7,000; *Total Annual Hours Requested:* 4,599,000.

To request copies of the proposed paperwork collections referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch,