Estimated Total Annual Burden Hours: 4,575.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, SW., Washington, DC. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by title.

In addition, requests for copies may be made and comments forwarded to the Reports Clearance Office over the Internet by sending message to rsargis@acf.dhhs.gov. Internet message must be submitted as an ASCII file without special characters or encryption.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the function 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) ways to enhance 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 of other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: May 23, 1996.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 96–13526 Filed 5–29–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 96N–0122]

Agency Information Collection Activities: Proposed Collections; Comment Request; Extension/ Reinstatement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish a notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements contained in existing FDA regulations governing temporary marketing permit applications, State petitions for exemption from preemption, State enforcement notifications, and reference amount petitions.

DATES: Submit written comments on the collections of information by July 29, 1996.

ADDRESSES: Submit written comments on the collections of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Charity B. Smith, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1686.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c). To comply with this requirement, FDA is publishing notice of the proposed collections of information listed below.

With respect to each of the following collections of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

1. Temporary Marketing Permit Applications (21 CFR 130.17(c) and (i)) (OMB Control Number 0910–0133—Extension)

Section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341) directs FDA to issue regulations establishing definitions and standards of identity for food ''whenever * * * such action will promote honesty and fair dealing in the interest of consumers.'' Under section 403(g) of the act (21 U.S.C. 343(g)), a food that is subject to a definition and standard of identity prescribed by regulation is misbranded if it does not conform to such definition and standard of identity. Section 130.17 (21 CFR 130.17) provides for the issuance by FDA of temporary marketing permits that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions and standards of identity. Section 130.17(c) specifies the information that a firm must submit to FDA to obtain a temporary marketing permit. The information required in a temporary marketing permit application under § 130.17(c) enables the agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable definitions or standards of identity. The information so obtained can be used in support of a petition to establish or amend the applicable definition or standard of identity to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a temporary marketing permit.

FDA estimates the burden of the temporary marketing permit application requirements as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
130.17	15	1.33	20	11.5	230

There are no capital costs or operating and maintenance costs associated with this collection.

The estimated number of temporary marketing permit applications and hours per response is an average based on the agency's experience with applications received from October 30, 1991, through September 30, 1994.

2. State Petitions for Exemption From Preemption (21 CFR 100.1(d)) (OMB Control Number 0910–0277—Reinstatement)

Under section 403A(b) of the act (21 U.S.C. 343–1(b)), States may petition FDA for exemption from Federal preemption of State food labeling and standard of identity requirements. Section 100.1(d) (21 CFR 100.1(d)) sets forth the information a State is required to submit in such a petition. The information required under § 100.1(d) enables FDA to determine whether the State food labeling or standard of identity requirement comports with the statutory criteria for exemption from Federal preemption.

FDA estimates the burden resulting from the requirements of § 100.1(d) as follows:

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100.1(d)	5	1	5	40	200

There are no capital costs or operating and maintenance costs associated with this collection.

Since the enactment of section 403A(b) of the act as part of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), FDA has received eight petitions for exemption from preemption. Based upon these submissions, FDA estimates that no more than five petitions will be submitted annually. Because § 100.1(d) implements a statutory information collection requirement, only the additional burden attributable to the regulation has been included in the estimate.

3. State Enforcement Notification (21 CFR 100.2(d)) (OMB Control Number 0910–0275—Reinstatement)

Section 310(b) of the act (21 U.S.C. 337(b)) authorizes States to enforce certain sections of the act in their own names, but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2(d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the act against a particular food located in the State. The information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the act.

FDA estimates the burden of complying with the enforcement notification requirement as follows:

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100.2(d)	5	1	5	2	10

There are no capital costs or operating and maintenance costs associated with this collection.

Based upon the small number of enforcement notifications received from the States since the enactment of section 310(b) of the act in 1990, FDA estimates that no more than five notifications will be submitted annually. Because 21 CFR 100.21(d) implements a statutory information collection requirement, only the additional burden attributable to the regulation has been included in the estimate.

4. Reference Amount Petitions (21 CFR 101.12(h)) (OMB Control Number 0910–0286—Reinstatement)

Section 403(q)(1)(A) of the act (21 U.S.C. 343(q)(1)(A)) requires that the label or labeling of food provide nutrition information that includes the serving size or, if the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food. In response to section 2(b)(1)(B) of the 1990 amendments, FDA issued regulations defining the serving size (or other unit of measure) for various types of food. Food producers are required to use the reference amount values provided in § 101.12 (21 CFR 101.12) and the rules for establishing serving sizes that are prescribed in § 101.9(b) (21 CFR 101.9(b)) to determine the appropriate serving size for their products; however, a manufacturer or other interested person may submit a petition to establish or amend the reference amount value for a food or to create a new food subcategory with its own reference amount. Section 101.12(h) sets forth the information the

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