SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by June 9, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Petitions for Affirmation of Generally Recognized As Safe (GRAS) Status—21 CFR 170.35(c)(1)—(OMB Control Number 0910–0132—Reinstatement)–

Under authority of sections 201, 402, 409, and 701 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 342, 348, and 371), FDA reviews petitions for affirmation as GRAS which are submitted on a voluntary basis by the food industry and other interested parties. Under section 409 of the act, the agency has the authority to regulate food additives. Section 201(s) of the act defines ''food additive'' and expressly excludes from the definitions substances GRAS for use in food.

Specifically under section 201(s) of the act, a substance is GRAS if it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, to be safe either through scientific procedures or through common use in food before 1958. The act has historically been interpreted to permit food manufacturers to make their own determination that use of a substance in food is GRAS. To implement the GRAS provisions of the act, FDA has issued procedural regulations under § 170.35(c)(1) (21 CFR 170.35(c)(1)). These regulations establish a process by which a person may obtain FDA concurrence with a GRAS determination; this concurrence is referred to as ''GRAS affirmation.'' These regulation set forth the information to be submitted to FDA to obtain agency concurrence that a substance is GRAS (§ 170.35(c)(1)).

GRAS petitions are reviewed by FDA to ascertain whether the available data establish that the intended use of the substance is GRAS based upon either a history of the safe use of the substance before 1958, or upon widely available safety data (scientific procedures). The GRAS affirmation process is a voluntary one, and there is some risk that FDA may not agree with the petitioner's GRAS determination. The GRAS petition process does provide a public procedure for coordinating GRAS determinations. The process reduces the potential for public health problems when substances are marketed based upon unwarranted safety determinations and allows a food manufacturer to rely on the lawful status of a substance that has been affirmed by FDA as GRAS.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.35(c)(1)	5	1	5	2,614 (average)	13,070

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

Dated: May 2, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12256 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0175]

BetzDearborn, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that BetzDearborn, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a copolymer of the sodium salt of acrylic acid with polyethyleneglycol allyl ether for use as a boiler water additive.

DATES: Written comments on the petitioner's environmental assessment by June 9, 1997.

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: Paulette M. Gaynor, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3079.

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 7A4541) has been filed by BetzDearborn, Inc., 4636 Somerton Rd., Trevose, PA 19053. The petition proposes to amend the food additive regulations in § 173.310 *Boiler water additives* (21 CFR 173.310) to provide for the safe use of a copolymer of acrylic acid and polyethyleneglycol allyl ether for use as a boiler water additive.

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 public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before (*insert date 30 days after date of publication in the* **Federal Register**), 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: April 16, 1997.

Alan M. Rulis,

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

[FR Doc. 97–12255 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96D–0028]

International Conference on Harmonisation; Guideline on Stability Testing for New Dosage Forms; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guideline entitled ''Stability Testing for New Dosage Forms.'' The guideline was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guideline addresses the generation of stability information for new dosage forms for submission to FDA by the owner of the original application. The guideline is an annex to the ICH guideline entitled ''Stability Testing of New Drug Substances and Products.''

DATES: Effective June 9, 1997. Written comments may be submitted at any time.

ADDRESSES: Submit written comments on the guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the guideline are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Regarding the guideline: Guiragos K. Poochikian, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1050.

Regarding ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In the **Federal Register** of March 6, 1996 (61 FR 9060), FDA published a draft tripartite guideline entitled ''Stability Testing for New Dosage Forms.'' The notice gave interested persons an opportunity to submit comments by June 4, 1996.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies at the ICH meeting held on November 5, 1996.

In the **Federal Register** of September 22, 1994 (59 FR 48754), FDA published a guideline entitled ''Stability Testing of New Drug Substances and Products.'' The guideline addresses the generation of stability information for submission to FDA in new drug applications for new molecular entities and associated drug products. For biotechnological/biological products, see ''Quality of Biotechnological/Biological Products: Stability Testing of Biotechnological/Biological Products'' (60 FR 43501, August 21, 1995).

This guideline is an annex to that guideline and addresses the generation of stability information for new dosage forms for submission to FDA by the owner of the original application, after the original submission for new drug substances and products.

This guideline represents the agency's current thinking on stability testing for new dosage forms. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

As with all of FDA's guidelines, the public is encouraged to submit written comments with new data or other new information pertinent to this guideline. The comments in the docket will be periodically reviewed and, where appropriate, the guideline will be amended. The public will be notified of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guideline. 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. The guideline and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this guideline is available on the Internet using the World Wide Web (WWW) (http://www.fda.gov/cder/guidance.htm).

The text of the guideline follows: