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: March 31, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–3349 Filed 4–6–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0457]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Generally Recognized as Safe: Notification Procedure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by May 8, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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

Substances Generally Recognized as Safe: Notification Procedure (OMB Control Number 0910–0342)—Extension

Section 409 of the act (21 U.S.C. 348) establishes a premarket approval requirement for ''food additives;'' section 201(s) of the act (21 U.S.C. 321(s)) provides an exemption from the definition of ''food additive'' and thus from the premarket approval requirement, for uses of substances that are generally recognized as safe (GRAS) by qualified experts. FDA is proposing a voluntary procedure whereby members of the food industry who determine that use of a substance satisfies the statutory exemption may notify FDA of that determination. The notice would include a detailed summary of the data and information that support the GRAS determination, and the notifier would maintain a record of such data and information. FDA would make the information describing the GRAS claim, and the agency's response to the notice, available in a publicly accessible file; the entire GRAS notice would be publicly available consistent with the Freedom of Information Act (FOIA) and other Federal disclosure statutes.

In the **Federal Register** of December 8, 2005 (70 FR 73009), FDA published a 60-day notice requesting public comment on the information collection provisions to which one comment was received. The comment states that obtaining the entire GRAS notification through the provisions of FOIA is not a practical means for interested persons to learn about the safety of a substance. The comment suggests that, to enhance the quality, utility, and clarity of the information to be collected, FDA should make publicly available a summary of data and information that supports the GRAS notice and also contains a discussion of any negative or inconsistent data.

FDA does not agree that obtaining information through the provisions of FOIA is impractical for interested persons. FDA also disagrees with the comment's suggestion that the agency make publicly available in the GRAS notification process a summary of data and information that supports the GRAS notice and also contains a discussion of any negative or inconsistent data, because such a summary would be duplicative of information available through FOIA procedures. This information collection is associated with the proposed rule entitled ''Notice of a Claim for GRAS Exemption Based on a GRAS Determination'' (the proposed rule) (62 FR 18938). Proposed § 170.36(c)(4) describes requirements for a detailed summary in the GRAS notification procedures. This section states that notifiers shall submit a detailed summary of the basis for the notifier's determination that a particular use of the notified substance is exempt from the premarket approval requirements of the act because such use is GRAS. Such determination may be based either on scientific procedures or on common use in food. Proposed § 170.36(c)(4)(i)(B) and 170.36(c)(4)(ii)(B) state that this detailed summary shall contain a comprehensive discussion of any reports of investigations or other information that may appear to be inconsistent with the GRAS determination. Proposed § 170.36(f)(1) states that all remaining data and information in the GRAS notice shall be available for public disclosure, in accordance with the provisions of FOIA, on the date the notice is received. This would include the detailed summary of the basis for the notifier's GRAS determination. To the extent that the comment suggests a change to the requirements of the proposed rule, FDA responds that such a request is outside the scope of the four collection of information topics on which the notice solicits comments and, thus, will not be addressed in this document. In response to the request for comments in that proposed rule, the commenter timely filed a similar comment. This comment will be considered in the development of the final rule.

Description of Respondents: Manufacturers of Substances Used in Food and Feed.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
170.36	50	1	50	150	7,500
570.36	10	1	10	150	1,500
Total					9,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per recordkeeper	Total hours
170.36(c)(v)	50	1	50	15	750
570.36(c)(v)	10	1	10	15	150
Total					900

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting requirement is for a proposed rule that has not yet been issued as a final rule. In developing the proposed rule, FDA solicited input from representatives of the food industry on the reporting requirements, but could not fully discuss with those representatives the details of the proposed notification procedure. FDA received no comments on the agency's estimate of the hourly reporting requirements, and thus has no basis to revise that estimate at this time. In 1998, FDA began receiving notices that were submitted under the terms of the proposed rule. Since it began receiving notices, FDA has received 12 in 1998, 23 in 1999, 30 in 2000, 28 in 2001, 26 in 2002, 23 in 2003, 20 in 2004, and 22 to date in 2005, notices annually. To date, the number of annual notices is less than FDA's estimate; however, the number of annual notices could increase when the proposed rule becomes final.

Dated: April 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5088 Filed 4–6–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement to Support a Single-Source Application—The Critical Path Institute: Collaborative Cardiovascular Drug Safety and Biomarker Research Program—ACTION; Availability of Sole Source Cooperative Agreement; Request for Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA), Office of the Commissioner (OC) is announcing its intent to accept and consider a single source application (RFA–FDA–OC–2006–1) for the award of a Cooperative Agreement to the Critical Path Institute. FDA anticipates providing up to $750,000 (direct and indirect costs combined) in fiscal year 2006 to support this multiphased research program that will include, but will not be limited to, the development of an infrastructure to support this program and subsequent related studies in cardiovascular disease and genomic/proteomic biomarker research, as stipulated by Congress.

Subject to the availability of Federal funds and successful performance, an additional 2 years of support up to $750,000(direct and indirect costs combined) per year may be available.

FDA will support the research covered by this notice under the authority of section 301 of the Public Health Service (PHS) Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance No. 93.103. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public.

The cooperative agreement ensures FDA's continued participation in the Collaborative Cardiovascular Drug Safety and Biomarker Research Program, as proposed by Congress and to be conducted under FDA's Critical Path Initiative. A goal of the Critical Path Initiative is to foster the development of new tools to both promote drug safety and accelerate the development of innovative new therapies, through appropriate collaboration with multiple parties. This collaborative research program is expected to be conducted in a multiphase process, leveraging resources and expertise from the awardee, other collaborators, and FDA to address public health needs involving cardiovascular disease and biomarker research.

II. Eligibility Information

Competition is limited because of Congressional mandate, the mission of the Critical Path Institute, its established collaboration with the University of Utah, and the combined ability of these parties to leverage existing databases, specimen repositories, clinical and other technical expertise in support of this program.

III. Application and Submission

For further information or a copy of the complete Request for Applications (RFA) contact Cynthia Polit, Grants Management Officer, Division of Contracts and Grants Management