impact of Head Start Programs. The September 28–29, 2005 meeting provides an opportunity for the Advisory Committee to provide advice on the analysis plans for the study following the June 2005 release on the first impact findings.

DATES: September 28 (9 a.m.–4 p.m.) and 29 (9 a.m.–12:30 p.m.), 2005.

Place: Bethesda Park Clarion Hotel, 8400 Wisconsin Avenue, Bethesda, MD 20814; Phone: (301) 654–1000; Fax: (301) 654–0751.

SUPPLEMENTARY INFORMATION: This meeting is open to the public and is barrier free. Meeting records will also be open to the public and will be kept at the Aerospace Building, 370 L'Enfant Promenade, SW., Washington, DC 20447. The Administration for Children and Families also intends to make material related to this meeting available on the Office of Planning, Research and Evaluation Web site (*http://www.acf.hhs.gov/programs/opre/index.html).* An interpreter for the deaf and hearing impaired will be available upon advance request by calling Xtria at 703–821–6182.

FOR FURTHER INFORMATION CONTACT: Maria Woolverton at 202–205–4039 for substantive information. Contact ACF Office of Public Affairs at 202–401–9215 for press inquiries. Contact Xtria at 703–821–6182 for logistical information.

Dated: September 7, 2005.

Naomi Goldstein,

Director, Office of Planning, Research and Evaluation, ACF.

[FR Doc. 05–18257 Filed 9–13–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0353]

Agency Information Collection Activities; Proposed Collection; Comment Request; Pharmaceutical Development Study

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 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed Pharmaceutical Development Study.

DATES: Submit written or electronic comments on the collection of information by November 14, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

Pharmaceutical Development Study

FDA's Office of Pharmaceutical Science (OPS) of the Center for Drug Evaluation and Research is proposing collaboration under a Cooperative Research and Development Agreement (CRADA) with Conformia Software, Inc. of Redwood City, CA (hereafter referred to as ''CRADA Partner''), to collect information using focus group discussions with firms to determine what factors may influence pharmaceutical development. These factors include development information bottlenecks, pilot plant information management, manufacturing science, information retrieval, quality systems and pre-clinical development challenges.

The FDA has introduced three new initiatives to help manufacturers develop higher quality drugs faster and cheaper. These initiatives include, but are not limited to, the following:

- Challenge and Opportunity on the Critical Path to New Medical Products (commonly referred to as the ''Critical Path Initiative'')
- Pharmaceutical cGMPs for the 21st Century—A Risk Based Approach
- International Conference on Harmonization (ICH) Steering Committee Guidelines—Pharmaceutical Development, ICH Q8 (Defining the Design Space)

The proposed study is designed to augment and support these initiatives by providing practical industry experiences and feedback to help FDA refine these initiatives. The scope of the proposed collaboration is aligned with FDA's ''Critical Path'' of development--specifically, the area between selection of drug candidates and commercial manufacturing.

Gathering information through this collaboration represents an opportunity for FDA to gain insights into current industry practices and provide the opportunity to better understand the specific factors that contribute to drug development difficulties. There is a perceived reluctance by industry to share information with regulatory bodies (outside of the formal review processes). Therefore, obtaining necessary and timely information through this collaboration will help the Critical Path Initiative progress.

The information collected will be used to create a clearer picture of current development bottlenecks, identify current state practices, highlight potential improvements in production, and provide feedback to FDA on the impact of current regulatory guidance.

Use of information: The three groups who will be involved with the study may benefit by the collection of this information as follows:

• Industry—Participants will compare current drug development practices and processes identified in the study with current FDA guidance. Companies will be able to gain a better understanding of the steps needed to achieve the operational goals introduced through the Critical Path, ICH-Q8, and Pharmaceutical cGMPs for the 21st Century.

• FDA—In its Critical Path initiative, FDA has called for better tools and techniques to be developed to help facilitate and improve productivity. The information gained will provide a better understanding of what steps will be needed to achieve this goal: To help companies reduce time spent in pharmaceutical development and speed the adoption of new technologies aimed at producing higher quality products at reduced costs.

• CRADA Partner—In collaboration with FDA, the CRADA partner will use research findings to better understand informational requirements of companies in the area of pharmaceutical development, particularly as they relate to accomplishing the goals of the three FDA initiatives described previously. This includes tools that may be utilized within the company environment to reduce bottlenecks and enhance communication of key pharmaceutical information, as well as tools that may assist FDA in the review of pharmaceutical development submissions.

Thus the study will assist all three party's understanding of the requirements to address the current state in dealing with pharmaceutical development challenges.

Confidentiality of Respondents: The CRADA Partner will provide an ''Informed Consent'' form to all companies that participate in the study. This form highlights and assures all participants that company-specific responses (or responses unique to a specific company) will not, under any circumstances, be divulged to other participants or the FDA without the company's prior consent. The CRADA Partner will also provide a Confidential Disclosure Agreement (CDA) to all participants assuring them confidentiality of disclosed information and adherence to the Privacy Act.

Participation in the study: The CRADA Partner will post on its Web site an invitation for industry to participate in the study. It will also fax the invitation to 20 of the top pharmaceutical companies and 20 of the top biotech companies. The invitation will be sent to the offices of regulatory affairs, research and development, and information management. The FDA will also post the CRADA abstract on its Web site along with instructions on how to participate in the study. Within each company separate, small focus groups will be formed for the three offices. Company management in consultation with the CRADA Partner will determine the actual makeup of the focus groups, but the objective is to have a cross-functional representation of experienced employees from each office.

Method of study: The CRADA Partner will conduct a preliminary phase of the study with individual representatives of nine firms (through dialogue with the Vice President (VP) of Development), who volunteer for participation in the study. VP of Development and the CRADA Partner will determine the specific representation from each company jointly, but the objective will be to include representatives from the office of regulatory affairs, research and development, and information technology. The results of these preliminary interviews will be used to refine the full study agenda, which will be used to conduct focus group discussions from 25 companies. Both the preliminary phase and the final study agenda will include review and comment by FDA technical and regulatory experts and CRADA Partner personnel.

The CRADA Partner will summarize interview findings for the full study and will remove references to specific firms, or information that could be used to identify specific firms, before sharing information with FDA. Follow-on questions will be identified by consultation between FDA and CRADA Partner personnel and these questions will be addressed in subsequent focus group interviews. Although companies are strongly encouraged to participate in these follow-on interviews, they may discontinue participation at any time.

As an incentive for companies to participate in the study, the CRADA Partner will prepare a confidential report which contrasts practices in each company in comparison with aggregated information from other companies. At all times, the identity of a participating firm will be limited to the company itself and to the CRADA Partner. This blinded methodology is an industry standard methodology for other areas of current state best practices research.

FDA personnel in collaboration will review final results with the CRADA Partner to determine appropriate next steps. These next steps may include training sessions with industry to increase industry awareness of pharmaceutical development practices and opportunities for improving these in conjunction with FDA's manufacturing and related industrialization initiatives; industry workshops to discuss and explore findings of the study; a publication or publications summarizing the study results; additional studies to further expand FDA's understanding of particular aspects of pharmaceutical development that may benefit from regulatory reform and steamlining; and adjustments to FDA's regulatory strategy to help remove unnecessary or unintended burdens on industry.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
25	1	25	20	500

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

Dated: September 7, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18163 Filed 9–13–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0349]

Agency Information Collection Activities: Proposed Collection; Comment Request; Food and Drug Administration Survey of Current Manufacturing Practices in the Food Industry

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 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed survey of current manufacturing practices in the food industry. The purpose of the proposed survey is to improve FDA's understanding of current food industry manufacturing practices. The information will be used to assess what impact, if any, new manufacturing requirements would make on the food industry.

DATES: Submit written or electronic comments on the collection of information by November 14, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (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 of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

FDA Survey of Current Manufacturing Practices in the Food Industry

The authority for FDA to collect the information derives from the FDA Commissioner's authority, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

FDA's regulations in part 110 of Title 21 of the Code of Federal Regulations (21 CFR part 110) describe the methods, equipment, facilities and controls for producing processed food, hereafter referred to as food CGMPs. As the minimum sanitary and processing requirements for producing safe and wholesome food, CGMPs are an important part of regulatory control of the nation's food supply. FDA believes that it is necessary to revisit and modernize the food CGMPs. Since the food CGMPs were last revised in 1986, there have been significant changes in food production technology and important advances in the understanding of foodborne illnesses. Accordingly, the agency will rigorously assess the impacts of any modernization policies on food facilities. To assess the impacts of the modernization policy, information is needed to help understand baseline or current industry practice. At present, however, FDA lacks baseline information on the nature of current manufacturing practices that would serve as part of a regulatory impact analysis.

FDA plans to conduct an Internet survey of all domestic FDA-registered facilities that primarily manufacture or process food and all foreign FDA-registered facilities that primarily manufacture or process food, which are located in those countries that are the largest food exporters to the United States: Japan, Canada, China, France, Italy and Mexico. The Internet survey will be supplemented by extended case study interviews with selected respondents from the survey. The survey and extended case studies will solicit detailed information about six key topics relevant to the food CGMPs modernization effort: employee training, sanitation and personal hygiene, allergen controls, process controls, post-production processing, and recordkeeping. Additionally, FDA will collect information on establishment characteristics, such as facility size and industry, which are expected to correlate with the presence or absence of various manufacturing practices, such as electronic recordkeeping, ongoing employee training in food safety, and product-to-label conformance procedures. The case study interviews will provide qualitative, in-depth information about various factors that influence decisions to implement these types of manufacturing practices, as well as about the circumstances that underlie the cost and effectiveness of such programs. The survey will be sent to every FDA-registered facility in the United States, Japan, Canada, China, France, Italy and Mexico that primarily manufactures or processes food products and that included an e-mail address with their registration. Participation will be voluntary and the respondent identifiers that would permit an association of specific responses to specific respondents will not be accessible to FDA.

The proposed Internet survey will collect the information from respondents electronically. With a custom-designed online survey system, responses will be entered directly into a computer database, eliminating the need for additional coding and data entry operations. Also, the system will ensure that conditional questions are asked in proper order, freeing the