ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burde hours
RI 15-month, parent child add-on survey	400	1	45 minutes or .75 hrs.	300
RI 15-month, youth survey	298	1	45 minutes or .75 hrs.	223.5
RI 15-month, direct child assessment	164	1	45 minutes or .75 hrs.	123

Estimated Total Annual Burden Hours: 646.5.

Additional Information

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF. E-mail: *Katherine_T._Astrich@omb.eop.gov.*

Dated: February 7, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–1294 Filed 2–10–06; 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; Submission for Office of Management and Budget Review; Comment Request; Pharmaceutical Development Study

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 March 15, 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: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Pharmaceutical Development Study

FDA's Office of Pharmaceutical Science 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 preclinical development challenges.

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 Harmonisation (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 experience 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 developmental 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 in this document. 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 FDA without the company's prior consent. The CRADA Partner will also provide a confidential disclosure agreement 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. 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. Followup 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 followup 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 that 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.

In the **Federal Register** of September 14, 2005 (70 FR 54388), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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	25	500

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

Dated: February 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1918 Filed 2–10–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Maternal and Child Health Services Title V Block Grant Program—Guidance and Forms for the Title V Application/Annual Report, OMB No. 0915–0172: Revision

The Health Resources and Services Administration (HRSA) proposes to revise the *Maternal and Child Health Services Title V Block Grant Program—Guidance and Forms for the Application/Annual Report.* The guidance is used annually by the 50 States and 9 jurisdictions in making application for Block Grants under Title V of the Social Security Act, and in preparing the required annual report. The proposed revisions follow and build on extensive consultation received from a workgroup convened to provide suggestions to improve the guidance and forms. In addition, the proposed revisions are editorial and ttechnical revisions based on the experience of the States and jurisdictions in using the guidance and forms since 2003.

Two new performance measures were developed (obesity in children aged 2 to 5 years; and smoking in the last trimester of pregnancy) and two existing performance measures were either removed entirely (low birth weight) or incorporated into an existing health status capacity indicator (eligible children receiving services under Medicaid). This will result in no net increase in the number of performance measures. In addition, the directions in the guidance for the Health Systems Capacity Indicators (HSCI) were expanded to enhance clarification. This proposed change will make it easier for the States to report on these indicators.

The existing electronic system used by the States to submit their Block Grant Application and Annual Report has also been enhanced. First, using the electronic system, the narrative from the prior year's submission is available online in the system so that the applicant need only edit those sections that have changed. This feature reduces burden by avoiding duplicating material. For national performance measures 2–6, the data obtained from the National Survey of Children with Special Health Care Needs are pre-populated which eliminates the need to retrieve and enter data from this survey, unless the States choose to use another data source. Also, notes from the prior year's submission are available to the States allowing for more efficient updating through edits rather then recreating them. Data are entered once (in a data entry field on a given form), and where those data are referenced elsewhere, the value is copied and displayed. The electronic system includes an automatic character counter that tells the user how many characters the States have left. This eliminates the need to independently track entries against the Maternal and Child Health Bureau's limits for each section to ensure compliance. The electronic system includes forms status checker and data alerts, which conduct automated checks on data validity, data consistency, and application completeness, as well as value tolerance checks. This feature facilitates application review and eliminates much of the previously required data cleaning activity. Also, this allows the user to obtain an immediate update at any point in time on the completeness and compliance of the application, reducing the need to conduct a review of the application. Data are saved directly to the HRSA server so that no manual transmission is required. Finally, the automatic commitment of data to the HRSA server eliminates the need for version control or data migration.

The estimated average annual burden per year is as follows for the Annual Report and Application without the Needs Assessment:

Type of respondent	Number of respondents	Responses per respondent	Burden hours per response	Total burden hours
States	50	1	297	14,868
Jurisdictions	9	1	120	1,077
Total	59			15,945

Burden in the 3 Year Reporting Cycle for the Annual Report and Application with Needs Assessment is:

Needs assessment	Number of respondents	Burden hours per response	Responses per respondent	Total burden hours
States/Jurisdictions	59	378.5	1	22,303
Total Average Burden for 3 year cycle				18,064

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Kraemer, Human Resources and Housing Branch, Office of Management