

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0353]

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Certifier	L. CLAWSON
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**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.

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**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 *[insert date 30 days after date of publication in the Federal Register]*.

**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 streamlining; 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<sup>1</sup>

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

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

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February 6, 2006.

*Jeffrey Shuren*

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