Name of Collection

Pharmaceutical Development Study

JUSTIFICATION

1. Circumstances That Make Information Collection Necessary

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).

2. Purpose of Information Collection

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

3. Use of Improved Information Technology

The study partner, Conformia, is a software development company and is knowledgeable and has access to the latest information technology for conduct and analysis of the study. Because of their experience in enterprise software development and the focus of the study, they will be able to evaluate the use of improved information technology in alleviating bottlenecks that face industry in pharmaceutical development.

4. Efforts to Identify Duplication and Availability of Similar Information

The Office of Pharmaceutical Science is FDA's leader in efforts to implement new initiatives for pharmaceutical development, including

- 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)

All of these are new initiatives related to the study goals. No efforts at this type of data collection have been undertaken as yet.

5. Small Business Considerations

The initial focus of the study will be on large pharmaceutical companies, where the size and complexity of these organizations is thought to be one of the factors contributing to developmental bottlenecks. However findings of the study will be provided to industry at large, including small companies, through industry workshops, publications, etc. Small companies tend to be among the most frequent participants at industry workshops and should benefit substantially from the findings. They may be able to use the findings to expand their own product development activities, by having insights provided on factors that may influence pharmaceutical market growth. In addition, generic manufacturers will be included in firms studied.

6. Consequences of Less Frequent Information Collection

Although there may be follow-on efforts to clarify initial study findings, this is planned to be a one-time collection effort.

7. Special Circumstances That Require Departures from 5 CFR 1320.5

8. Efforts to Consult with Non-Agency Personnel

As required under section 3506 (c)(2)(B) of the Paperwork Reduction Act, FDA provided an opportunity for public comments on February 11, 2004, (68 FR 6668). No comments were received in response to this notice.

9. Payment or Gifts

There are no payments or gifts as part of this study.

10. Assurances of Confidentiality

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.

11. Additional Assurances of Privacy

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.

12. Estimates of the Burden Collection

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
--	25	1	25	20	500
Total	25	1	25	20	500

13. Cost to Respondents

Respondents' contributions will be limited to time spent in participating in focus group sessions and related time.

14. Cost to the Federal Government

All costs for the conduct of the study are to be born by the CRADA partner. The Agency will participate in interpretation of the results and is expect to benefit substantially from the study findings.

15. Reason for Changes in Burden

This is a new collection and one time collection

16. Plans for Statistical Use

Because of the small sample size, statistical analysis is not expected to be a significant factor in the study. However statistical analysis will be applied to study results when appropriate.

17. Approval for Not Displaying Expiration Date

18. Exception to the Certification statement; Item 19, OMB Form 83-1