SUPPORTING STATEMENT

Guidance for Industry on Pharmacogenomic Data Submissions

OMB Control Number 0910-0557

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection approval request is for a Food and Drug Administration (FDA) guidance for industry entitled "Pharmacogenomic Data Submissions." The guidance provides recommendations to sponsors submitting or holding investigational new drug applications (INDs), new drug applications (NDAs), or biologic licensing applications (BLAs) on what pharmacogenomic data should be submitted to the agency during the drug development process. Sponsors holding and applicants submitting INDs, NDAs, or BLAs are subject to FDA requirements for submitting to the agency data relevant to drug safety and efficacy (§§ 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12).

The guidance interprets FDA regulations for IND, NDA, or BLA submissions, clarifying when the regulations require pharmacogenomics data to be submitted and when the submission of such data is voluntary. The pharmacogenomic data submissions described in the guidance that are required to be submitted to an IND, NDA, BLA, or annual report are covered by the information collection requirements under parts 312, 314, and 601 (21 CFR parts 312, 314, and 601) and are approved by OMB under control numbers 0910-0014 (part 312—INDs); 0910-0001 (part 314--NDAs and annual reports); and 0910-0338 (part 601—BLAs).

The guidance distinguishes between pharmacogenomic tests that may be considered valid biomarkers appropriate for regulatory decisionmaking, and other, less well-developed

exploratory tests. The submission of exploratory pharmacogenomic data is not required under the regulations, although the agency encourages the voluntary submission of such data.

The guidance describes the voluntary genomic data submission (VGDS) that can be used for such a voluntary submission. The guidance does not recommend a specific format for the VGDS, except that such a voluntary submission be designated as a VGDS. The data submitted in a VGDS and the level of detail should be sufficient for FDA to be able to interpret the information and independently analyze the data, verify results, and explore possible genotype-phenotype correlations across studies. FDA does not want the VGDS to be overly burdensome and time-consuming for the sponsor.

2. Purpose and Use of Information Collection

The guidance is intended to facilitate scientific progress in the field of pharmacogenomics and to facilitate the use of pharmacogenomic data in informing regulatory decisions. The guidance provides recommendations to sponsors holding INDs, NDAs, and BLAs on what pharmacogenomic data to submit to the agency during the drug development process, the format of submissions, and how the data will be used in regulatory decisionmaking.

3. Use of Improved Information Technology and Burden Reductioon

To improve the use of information technology in the submission of marketing applications for human drugs and related reports, FDA has developed and issued guidances for industry on electronic submissions. These guidance documents are available on FDA's Web site at http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/Guidances/

default.htm.

4. Efforts to Identify Duplication and Use of Similar Information

The information collection requested under the guidance does not duplicate any other information collection.

5. Impact on Small Businesses or Other Small Entities

Although new drug development is typically an activity completed by large multinational drug firms, the information collection requested under the guidance applies to both small and large companies. Under the Regulatory Flexibility Act, FDA regularly analyzes regulatory options that would minimize any significant impact on small entities. FDA also assists small businesses in complying with regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

Sponsors holding INDs, NDAs, and BLAs would not be provided essential guidance on what pharmacogenomic data to submit to the agency during the drug development process, the format of submissions, and information on how the data will be used in regulatory decisionmaking.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5(d)(2)

This guidance contains no inconsistency with the guidelines in 5 CFR 1320.5(d)(2).

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the

Agency

In the Federal Register of November 4, 2010 (75 FR 67983), FDA published a notice requesting comment on voluntary genomic data submissions. We received no comments.

9. Explanation of Any Payment or Gift to Respondents

FDA has not provided and has no intention to provide any payment or gift to respondents under this guidance.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of the information submitted under this guidance is protected under 21 CFR 312.130 and 314.430 and under 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under section 310(j) of the Federal Food, Drug, and Cosmetic Act.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12a. Estimates of Annualized Burden Hours

FDA has estimated the burden of preparing a voluntary submission described in the guidance that should be designated as a VGDS. Based on FDA's experience with this guidance over the past few years, and on FDA’s familiarity with sponsors' interest in submitting pharmacogenomic data during the drug development process, FDA estimates that approximately

seven sponsors will submit approximately seven VGDSs and that, on average, each VGDS will take approximately 50 hours to prepare and submit to FDA.

Table 1.--Estimated Annual Reporting Burden

	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Voluntary Genomic Data Submissions	7	1	7	50	350

12b. Estimates of Annualized burden costs

Type of respondent	Total burden hours	Hourly wage rate	Total respondent costs
Industry	350	75.00	$26,250.00

FDA has estimated an average industry wage rate of $75.00 per hour for preparing and submitting the information collection under this guidance. Using the averaged wage rate of $75.00 per hour, and multiplied times the total hour burden estimated above, the total cost burden to respondents is $26,250 (350x $75).

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

We do not anticipate any other costs, including capital costs or operating and maintenance costs, resulting from the information collection in the guidance.

14. Annualized Cost to the Federal Government

FDA estimates that the review of the VGDSs by FDA staff would require approximately 3 FTEs. Based on a cost of approximately $154,000 per FTE, FDA estimates the cost to be $462,000.

15. Explanation for Program Changes or Adjustments

Based on our experience with the submission of VGDSs under this guidance over the past few years, the number of annual responses has been reduced from 10 to 7 because of reduced submissions. There are no other changes or adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no publications.

17. Reason(s) Display of OMB Expiration Date Is Inappropriate

The agency is not seeking to display the expiration date for OMB approval of the information collection.

18. Exceptions to the Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB Form 83-I.