Food and Drug Administration
Guidance for Industry (GFI): Special Protocol Assessment
OMB Control No. 0910-0470
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The information collection supports agency guidance entitled, "*Special Protocol Assessment: Guidance for Industry*." The guidance describes agency procedures to evaluate issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies. The guidance describes procedures for sponsors to request special protocol assessment and for the agency to act on such requests. The guidance provides information on how the agency will interpret and apply provisions of the Food and Drug Administration Modernization Act of 1997 and the specific Prescription Drug User Fee Act of 1992 (PDUFA) goals for special protocol assessment associated with the development and review of PDUFA products.

Specifically, the guidance describes two collections of information: (a) The submission of a notice of intent to request special protocol assessment of a carcinogenicity protocol; and (b) the submission of a request for special protocol assessment.

A. Notification for a Carcinogenicity Protocol

As described in the guidance, a sponsor interested in agency assessment of a carcinogenicity protocol should notify the appropriate division in FDA's Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) of an intent to request special protocol assessment at least 30 days prior to submitting the request. With such notification, the sponsor should submit relevant background information so that the agency may review reference material related to carcinogenicity protocol design prior to receiving the carcinogenicity protocol.

B. Request for Special Protocol Assessment

In the guidance, CDER and CBER ask that a request for special protocol assessment be submitted as an amendment to the investigational new drug application (IND) for the underlying product and that it be submitted to the agency in triplicate with Form FDA 1571. The agency also suggests that the sponsor submit the cover letter to a request for special protocol assessment via facsimile to the appropriate division in CDER or CBER. Agency regulations (§ 312.23(d)) state that information provided to the agency as part of an IND is to be submitted in triplicate and with the appropriate cover form, Form FDA 1571. An IND is submitted to FDA under existing regulations in part 312 (21 CFR part 312), which specifies the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of investigational drugs and biological products. The information collection requirements resulting

from the preparation and submission of an IND under part 312 have been estimated by FDA and the reporting and recordkeeping burden has been approved by OMB under OMB Control Number 0910-0014.

FDA suggests that the cover letter to the request for special protocol assessment be submitted via facsimile to the appropriate division in CDER or CBER to enable agency staff to prepare for the arrival of the protocol for assessment. The agency recommends that a request for special protocol assessment be submitted as an amendment to an IND to ensure that each request is kept in the administrative file with the entire IND, and to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the appropriate agency official to monitor progress on the evaluation of the protocol and to ensure that appropriate steps will be taken in a timely manner.
CDER and CBER have determined and the guidance recommends that the following information should be submitted to the appropriate Center with each request for special protocol assessment so that the Center may quickly and efficiently respond to the request:

2. Purpose and Use of the Information Collection

The information allows FDA to evaluate drug study protocols including: (1) The role of the study in the overall development of the drug; (2) information supporting the proposed trial, including power calculations, the choice of study endpoints, and other critical design features; (3) regulatory outcomes that could be supported by the results of the study; (4) final labeling that could be supported by the results of the study; and (5) for a stability protocol, product characterization and relevant manufacturing data.

3. Use of Improved Information Technology and Burden Reductions

The Food and Drug Administration Modernization Act of 1997 (FDAMA) and the Prescription Drug User Fee Act (PDUFA) II reauthorization mandate that the agency develop and update its information management infrastructure to allow the paperless receipt and processing of investigational new drug applications and new drug applications, as defined in PDUFA, and related submissions. FDA has issued a final rule requiring the submission of labeling for human prescription drugs and biologics in electronic format. FDA has also issued several guidances describing how to make voluntary electronic submissions to the agency, including a guidance on general considerations for electronic submissions entitled "*Providing Regulatory Submissions in Electronic Format--General Considerations*." The general considerations guidance included a description of the types of electronic file formats that we are able to accept for processing, reviewing, and archiving electronic documents. This guidance may be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative 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 small as well as 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

As explained above, the guidance sets forth procedures adopted by CDER and CBER to evaluate issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies. The guidance describes procedures for sponsors to request special protocol assessment and for the agency to act on such requests.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

There are no special circumstances for this collection of information.

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

In the Federal Register of November 18, 2016 (81 FR 81776), the agency requested comments on the proposed collection of information. No comments were received that pertained to the information collection analysis.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are provided 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 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 act.

11. Justification for Sensitive Questions

The information collection contains no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours And Costs

12a. Annualized Hour Burden Estimate

Notification for a Carcinogenicity Protocol. Based on the number of notifications for carcinogenicity protocols and the number of carcinogenicity protocols currently submitted to CDER and CBER, CDER estimates that it will receive approximately 52 notifications of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately 28 sponsors. CBER estimates that it will receive approximately one notification of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately one sponsor. The hours per response, which is the estimated number of hours that a sponsor would spend preparing the notification and background information to be submitted in accordance with the guidance, is estimated to be approximately 8 hours.

Requests for Special Protocol Assessment. Based on the number of requests for special protocol assessment currently submitted to CDER and CBER, CDER estimates that it will receive approximately 211 requests for special protocol assessment per year from approximately 112 sponsors. CBER estimates that it will receive approximately 9 requests from approximately 7 sponsors. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for special protocol assessment, including the time it takes to gather and copy questions to be posed to the agency regarding the protocol and data, assumptions, and information needed to permit an adequate evaluation of the protocol. Based on the agency's experience with these submissions, FDA estimates approximately 15 hours on average would be needed per response.

FDA estimates the burden of this collection as follows:

Table 1. Estimated Annual Reporting Burden[1]

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Notification for Carcinogenicity Protocols	29	1.8	53	8	424
Requests for Special Protocol Assessment	119	1.8	220	15	3,300
TOTAL					3,724

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

12b. Annualized Cost Burden Estimate

FDA's Economics Staff estimates an average industry wage rate of $85 per hour (averaged from wages for upper management, middle management, and clerical support, plus overhead and personnel benefits) for preparing and submitting the information requested under the guidance. Using the averaged wage rate of $85 per hour, and multiplied times the total hour burden estimated above (3,724), the total cost burden to respondents is approximately $316,540.

13. Estimates of Other Total Annual Costs Burden to Respondents and/or Recordkeepers/Capital Costs

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

14. Estimates of Annualized Cost to the Federal Government

Costs to the Federal Government are absorbed under existing resource allocations.

15. Explanation for Program Changes or Adjustments

The adjustment in burden is the result of a decrease in the submissions described above over the past 3 years.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no such plans.

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

Display of OMB Expiration Date is appropriate.

18. Exception to the Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.