UNITED STATES FOOD & DRUG ADMINISTRATION

Formal Dispute Resolution; Appeals Above the Division Level

OMB Control No. 0910-0430 - REVISION

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) guidance regarding scientific and procedural dispute resolution in our Center for Drug Evaluation and Research (CDER) and our Center for Biologics Evaluation Research (CBER). Congress enacted section 562 of the Federal Food, Drug, and Cosmetic Act (FFDCA or the act)(21 U.S.C. 360bbb-1), directing us to ensure that adequate dispute resolution procedures are in place for the appropriate review of scientific controversies between the FDA and members of regulated industry. Accordingly, we developed the guidance document entitled, "*Formal Dispute Resolution: Sponsor Appeals Above the Division Leve*l," available at https://www.fda.gov/downloads/drugs/guidances/ucm343101.pdf. The guidance document describes procedures for formally appealing such disputes to the office or center level and for submitting information to assist center officials in resolving the issue or issues presented.

Specifically, the guidance document provides information on how we interpret and apply provisions of the existing regulations regarding internal agency review of decisions (§10.75 (21 CFR 10.75)) and dispute resolution during the investigational new drug (IND) process (§312.48 (21 CFR 312.48)) and the new drug application/abbreviated new drug application (NDA/ANDA) process (§314.103 (21 CFR 314.103)). In addition, the guidance document provides information on how we will interpret and apply the specific Prescription Drug User Fee Act (PDUFA) goals for major dispute resolution associated with the development and review of PDUFA products. In the guidance document, CDER and CBER ask that a request for formal dispute resolution be submitted as an amendment to the application for the underlying product and that it be submitted in triplicate with the appropriate form attached, either Form FDA 1571 or Form FDA 356h (forms approved under OMB Control Nos. 0910-0014 and 0910-0338, respectively). The guidance recommends that a request be submitted as an amendment in this manner to ensure that each request is kept in the administrative file with the entire underlying application and to ensure that pertinent information about the request is entered into the appropriate tracking databases.

Finally, we have updated the guidance to revise dispute resolution performance goals as established under the FDA Reauthorization Act (user fee reauthorization) in August 2017. While the performance goals revise timelines for FDA review of dispute resolution, no changes have been made to the information collection elements.

We therefore request extension of OMB approval of the information collection provisions found in the subject guidance document.

2. Purpose and Use of the Information Collection

The guidance document provides instruction to respondents on how to resolve scientific dispute appeals above the division level regarding products reviewed by CDER and CBER. We believe that the information recommended in the guidance will facilitate agency review of dispute appeals and focus associated discussions.

3. Use of Improved Information Technology and Burden Reduction

As explained in the guidance, because requests are submitted as part of an underlying product application, submissions are made electronically. We are unaware of any technological burdens associated with the information collection.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. While we have developed additional guidance to assist manufacturers of FDA-regulated products with other areas of dispute resolution, this collection is limited in scope and subject matter to those topics associated with appeals above the division level within CDER or CBER.

5. Impact on Small Businesses or Other Small Entities

We believe the information collection poses no undue burden on small entities. At the same time, we assist small businesses in complying with our requirements through our Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide a Small Business Guide on our website at: http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.

6. Consequences of Collecting the Information Less Frequently

As explained above, CDER and CBER have determined that the information specified in the guidance should be submitted to the appropriate center with each request for dispute resolution so that the Center may quickly and efficiently respond to the request.

7. Special Circumstances Relating to the Guidelines of 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 accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the Federal Register of August 20, 2018 (83 FR 42127). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is provided to respondents to the information collection.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of the information submitted under this information collection is protected under 21 CFR 314.430, 21 CFR part 601, and 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)).

11. Justification for Sensitive Questions

No questions of a sensitive nature are included in the information collection.

12. Estimates of Annualized Burden Hours and Costs

We estimate the burden of the information collection as follows:

12a. Annualized Hour Burden Estimate

Based on our experience with the information collection, we expect most persons seeking formal dispute resolution will have gathered the materials recommended in the guidance when identifying the existence of a dispute and, thus, we assume 8 hours is attributable to this activity. Upon our review of submissions received over the past three years, we estimate that CDER receives 17 requests annually, while CBER receives 1 request. This is reflected in Table 1, below.

Table 1.-- Estimated Annual Reporting Burden[1]

Requests for Formal Dispute Resolution	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
CDER	12	1.42	17	8	136
CBER	1	1	1	8	8
Total					144

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

12b. Annualized Cost Burden Estimate

We estimate an average industry wage rate of $80.00 per hour for preparing and submitting the information requested under the guidance. Multiplying this figure by the total number of burden hours estimated above, we calculate a total cost burden to respondents of $11,520.

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate no additional costs associated with the receipt/review by FDA of the information submitted consistent with recommendations in the guidance.

15. Explanation for Program Changes or Adjustments

The information collection reflects both changes and adjustment. We have decreased our burden estimate by 14 responses and 112 hours based on the number of dispute requests received since last OMB review. In addition, since last OMB approval, we have updated the guidance document to revise dispute resolution performance goals as established under the FDA Reauthorization Act (user fee reauthorization) in August 2017. While the performance goals revise timelines for FDA review of dispute resolution, no changes have been made to the information collection elements.

16. Plans for Tabulation and Publication and Project Time Schedule

We have no such plans.

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

Display of the OMB expiration date as required by 5 CFR 1320.5 is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.