

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0248]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 March 27, 2019.

ADDRESSES: 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: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0430. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRASStaff@fda.hhs.gov.

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.

Formal Dispute Resolution; Appeals Above the Division Level; OMB Control Number 0910-0430—Extension

This approval request is for information collection found in the FDA guidance document entitled, "Formal Dispute Resolution: Sponsor Appeals Above the Division Level Guidance for Industry and Review Staff." The guidance document discusses the process for formally resolving scientific and procedural disputes in FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics

Evaluation and Research (CBER) that cannot be resolved at the division level. 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. The guidance document provides information on how the Agency will 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 the Agency 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. The guidance document is available on our website at: <https://www.fda.gov/downloads/drugs/guidances/ucm343101.pdf>.

Existing regulations, which appear primarily in parts 10, 312, and 314 (21 CFR parts 10, 312, and 314), establish procedures for the resolution of scientific and procedural disputes between interested persons and the Agency, CDER, and CBER. All Agency decisions on such matters are based on information in the administrative file (§ 10.75(d)). In general, the information in an administrative file is collected under existing regulations in part 312 (OMB control number 0910-0014), part 314 (OMB control number 0910-0001), and part 601 (21 CFR part 601) (OMB control number 0910-0338), which specify the information manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of drugs and biological products. This information is usually submitted as part of an IND, NDA, or biologics license application (BLA), or as a supplement to an approved application. Although FDA already possesses in the administrative file the information that would form the basis of a decision on a matter in dispute resolution, the submission of information regarding the request itself and the data and information that the requestor relies on in the appeal would facilitate timely resolution of the dispute. The guidance document describes the following collections of information not expressly specified under existing regulations: The submission of the request for dispute resolution as an amendment to the

application for the underlying product, including the submission of supporting information with the request for dispute resolution.

Agency regulations (§§ 312.23(a)(11) and (d), 314.50, 314.94, and 601.2) state that information provided to the Agency as part of an IND, NDA, ANDA, or BLA must be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs, ANDAs, and BLAs. Both forms have valid OMB control numbers as follows: Form FDA 1571 (OMB control number 0910-0014) and Form FDA 356h (OMB control number 0910-0338).

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 to the Agency in triplicate with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The Agency recommends that a request be submitted as an amendment in this manner for two reasons: (1) To ensure that each request is kept in the administrative file with the entire underlying application; and (2) 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 resolution of the dispute and to ensure that appropriate steps will be taken in a timely manner.

CDER and CBER have determined and the guidance document recommends that the following information 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: (1) A brief but comprehensive statement of each issue to be resolved, including a description of the issue, the nature of the issue (*i.e.*, scientific, procedural, or both), possible solutions based on information in the administrative file, whether informal dispute resolution was sought prior to the formal appeal, whether advisory committee review is sought, and the expected outcome; (2) a statement identifying the review division/office that issued the original decision on the matter and, if applicable, the last Agency official that attempted to formally resolve the matter; (3) a list of documents in the administrative file or additional copies of such documents that are deemed necessary for resolution of the issue or issues; and (4) a statement that the previous supervisory level has already

had the opportunity to review all of the material relied on for dispute resolution. The information the Agency suggests submitting with a formal request for dispute resolution consists of: (1) Statements describing the issue from the perspective of the person with a dispute; (2) brief statements describing the history of the matter; and (3) the documents previously submitted to FDA under an OMB approved collection of information.

Based on FDA's experience with dispute resolution, the Agency expects that most persons seeking formal dispute resolution will have gathered the materials listed previously when identifying the existence of a dispute with the Agency. Consequently, FDA anticipates that the collection of information attributed solely to the guidance document will be minimal.

Provided in this document is an estimate of the annual reporting burden for requests for dispute resolution.

Based on data collected from review divisions and offices within CDER and CBER, FDA estimates that approximately 12 sponsors and applicants (respondents) will submit requests for formal dispute resolution to CDER annually and approximately 1 respondent will submit requests for formal dispute resolution to CBER annually.

The total annual responses are the total number of requests submitted to CDER and CBER in 1 year, including requests for dispute resolution that a single respondent submits more than one time. FDA estimates that CDER receives approximately 17 requests annually and CBER receives approximately 1 request annually. 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 formal dispute resolution in accordance

with the guidance document, including the time it takes to gather and copy brief statements describing the issue from the perspective of the person with the dispute, brief statements describing the history of the matter, and supporting information that has already been submitted to the Agency. Based on experience, FDA estimates that approximately 8 hours, on average, would be needed per response. Therefore, FDA estimates that 8 hours will be spent per year by respondents requesting formal dispute resolution in accordance with the guidance document.

In the **Federal Register** of August 20, 2018 (83 FR 42127), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Requests for formal dispute resolution	Number of respondents	Number 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.

The burden for this information collection has changed since the last OMB approval. Our burden estimate reflects a decrease in burden by 14 records and 112 hours. This adjustment corresponds to a decrease in the number of requests received over the last few years.

Dated: February 19, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is

announcing the availability of additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products" that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by April 26, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the