

made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Sara Rothman, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3110.

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Background**

FDA is announcing the availability of a final guidance for industry entitled

"Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." On November 27, 2013, President Obama signed the Drug Quality and Security Act (DQSA) into law (Pub. L. 113-54). The DQSA added a new section, 503B, to the FD&C Act (21 U.S.C. 353b). Under section 503B(b), a compounder can register as an outsourcing facility with FDA. Section 503B(d)(4) of the FD&C Act defines an outsourcing facility, in part, as a facility that complies with all of the requirements of section 503B, including registering with FDA as an outsourcing facility and paying associated fees. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs).

Under section 503B(b)(5), an outsourcing facility must submit adverse event reports to FDA in accordance with the content and format requirements established through guidance or regulation under 21 CFR 310.305 (or any successor regulations). This guidance explains how FDA intends to implement § 310.305 with respect to outsourcing facilities.

In the **Federal Register** of February 19, 2015 (80 FR 8872), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on May 20, 2015. FDA received seven comments on the draft guidance.

In response to received comments or on its own initiative, FDA made several changes to clarify particular points and to provide updated information.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create any rights for any person and is not binding on FDA or the public. An alternative approach can be used if such approach satisfies the requirements of the applicable statutes and regulations.

#### **II. Paperwork Reduction Act**

This guidance contains collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information have been approved under OMB control number 0910-0800.

#### **III. Electronic Access**

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: October 2, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-25622 Filed 10-7-15; 8:45 am]

**BILLING CODE 4164-01-P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **Food and Drug Administration**

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

#### **Agency Information Collection Activities; Proposed Collection; Submission for Office of Management and Budget Review; 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) 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 November 9, 2015.

**ADDRESSES:** You may submit comments as follows:

#### **Electronic Submissions**

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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 manner detailed (see "Written/Paper Submissions" and "Instructions").

### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2012-N-0248 for "Agency Information Collection Activities; Proposed Collection; Submission for Office of Management and Budget Review; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available

for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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 [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0430.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@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.

### Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level OMB Control Number 0910-0430—Extension

This information collection approval request is for FDA guidance on the process for formally resolving scientific and procedural disputes in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) that cannot be resolved at the division level. The guidance 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(s) presented. The guidance 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 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.

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 that 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. While 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 particular information regarding the request itself and the data and information relied on by the requestor in the appeal would facilitate timely resolution of the dispute. The guidance describes the following collection 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 is to 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: FDA Form 1571—OMB control number 0910–0014, and FDA Form 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: 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. 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 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(s); 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 that 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 will be minimal.

*Description of Respondents:* A sponsor, applicant, or manufacturer of a drug or biological product regulated by the Agency under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act who requests formal resolution of a scientific or procedural dispute.

In the **Federal Register** of June 2, 2015 (80 FR 31386), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

*Burden Estimate:* 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 eight sponsors and applicants (respondents) submit requests for formal dispute resolution to CDER annually and approximately one respondent submits 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 31 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 this guidance, 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 under the guidance.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Requests for formal dispute resolution	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER .....	8	2	31	8	248
CBER .....	1	1	1	8	8
Total .....					256

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 2, 2015.  
**Leslie Kux,**  
*Associate Commissioner for Policy.*  
[FR Doc. 2015–25623 Filed 10–7–15; 8:45 am]  
**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**National Institutes of Health**  
**National Heart, Lung, and Blood Institute Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended (5 U.S.C. App.), notice is hereby given of the following meetings.  
The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,