

stage process described in the Cures Act. This consists of the following stages: The Letter of Intent, the Qualification Plan, and the Full Qualification Package. These stages are discussed in detail in section III of the final guidance.

The Cures Act includes transparency provisions that require the Agency to make information with respect to qualification submissions publicly available. A description of information that is made public on the Agency's website is provided in section II of the final guidance.

CDER and CBER have considered public comments made during the December 11, 2018, public meeting and submitted to the docket in developing the draft guidance of the same title published on December 16, 2019 (84 FR 68460). The Agency received various comments to the docket in response to the publication of the draft guidance and has considered those comments in developing this final guidance. Changes made in the final guidance in response to comments include requests for additional clarity on the qualification process, support for the proposed time frames, and requests to reference specific programs' content element outlines in the guidance. This final guidance meets the Cures Act's requirement to finalize guidance on the section 507 qualification process and affirms the BEST glossary as the taxonomy for classifying types of DDTs. This guidance does not address evidentiary standards for purposes of DDT qualification. It also does not address the qualification of medical device development tools or other programs under the Center for Devices and Radiological Health oversight, which are not addressed in section 507 of the FD&C Act.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the "Qualification Process for Drug Development Tools." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The previously approved collections of

information are subject to review by OMB under the PRA. The collections of information pertaining to submissions of investigational new drug applications have been approved under OMB control number 0910–0014; the collections of information pertaining to submissions of new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001; and the collections of information pertaining to submissions of biologics license applications in 21 CFR part 601 have been approved under OMB control number 0910–0338.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>, or <https://www.regulations.gov>.

Dated: November 19, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2017–D–5739]

#### Formal Meetings Between the Food and Drug Administration and Abbreviated New Drug Application Applicants of Complex Products Under Generic Drug User Fee Amendments; Guidance 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 a final guidance for industry entitled "Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA." This guidance describes an enhanced pathway for discussions between FDA and a prospective applicant preparing to submit (or an applicant that has submitted) to FDA an abbreviated new drug application (ANDA) for a complex product. Specifically, this guidance provides information on requesting and conducting product development meetings, presubmission meetings, and

midreview cycle meetings with FDA. This guidance will assist applicants in generating and submitting a meeting request and the associated meeting package to FDA for complex products to be submitted under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and as contemplated in the commitments made by FDA in connection with the reauthorization of the Generic Drug User Fee Amendments for Fiscal Years (FYs) 2018–2022 (GDUFA II). This guidance finalizes the draft guidance of the same title issued on October 3, 2017.

**DATES:** The announcement of the guidance is published in the **Federal Register** on November 25, 2020.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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 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):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2017-D-5739 for “Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

• **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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this 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-

0002. 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:** Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993-0002, 240-402-7930, [elizabeth.giaquinto@fda.hhs.gov](mailto:elizabeth.giaquinto@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance for industry entitled “Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA.” This guidance describes an enhanced pathway for discussions between FDA and a prospective applicant preparing to submit (or an applicant that has submitted) to FDA an ANDA for a complex product. Specifically, this guidance provides information on requesting and conducting product development meetings, presubmission meetings, and midreview cycle meetings with FDA.

This guidance reflects a unified approach to all formal meetings between FDA and ANDA applicants or prospective ANDA applicants for complex products. This guidance is intended to assist ANDA applicants and prospective ANDA applicants in generating and submitting to FDA a meeting request and the associated meeting package for these complex products, as defined in this guidance, to be submitted under section 505(j) of the FD&C Act (21 U.S.C. 355(j)) and as contemplated in GDUFA II.

As part of the commitments FDA made in connection with GDUFA II, FDA agreed to develop a program to assist ANDA applicants and prospective ANDA applicants of complex products before the submission of an ANDA to FDA. As stated in the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022 (GDUFA II Goals or Commitment Letter available at <https://www.fda.gov/media/101052/download>), this pre-ANDA program is intended to clarify regulatory expectations for prospective applicants early in product development, assist applicants to develop more complete submissions, promote a more efficient and effective ANDA review process, and reduce the number of review cycles required to obtain ANDA approval, particularly for complex products (GDUFA II Commitment Letter at 14).

To facilitate development of complex products that may be submitted in an ANDA, FDA and industry agreed to a series of meetings between ANDA applicants and prospective ANDA applicants and FDA to discuss the proposed complex product and support submission of a high-quality, approvable ANDA.

In addition to developing a robust pre-ANDA program, FDA agreed to respond to requests for and conduct meetings related to the development of complex products submitted on or after October 1, 2017, within specific timeframes.

This guidance finalizes the draft guidance entitled “Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA” issued on October 3, 2017 (82 FR 46071). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance were made to address requests for clarity in seeking such meetings, as described in the guidance, with FDA.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

##### **II. Paperwork Reduction Act of 1995**

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The previously collections of information are subject to review by OMB under the PRA. The collections of information for meetings related to generic drug development have been approved under OMB control number 0910-0797.

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

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

Dated: November 18, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2009–N–0380]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Product Jurisdiction and Combination Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) 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 (PRA) of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by December 28, 2020.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0523. 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, [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.

#### Product Jurisdiction and Combination Products—21 CFR Part 3

*OMB Control Number 0910–0523—Revision*

This information collection supports implementation of section 503(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353(g)), as amended by the 21st Century Cures Act (Pub. L. 114–255) (Cures Act), section 563 of the FD&C Act (21 U.S.C. 360bbb–2) added to the FD&C Act by the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), and Agency regulations in 21 CFR part 3. Section 503(g) of the FD&C Act expressly provides for the regulation of combination products, including how primary Agency responsibility shall be designated for such products and how certain submissions regarding such products may be made to the Agency. Section 563 of the FD&C Act requires FDA to classify products as biological products, devices, drugs, or combination products and to assign products to an Agency component for regulation, in response to requests for designation (RFDs) submitted by product sponsors. We updated our regulations in 21 CFR part 3 in 2005 to clarify the meaning of the statutory term “primary mode of action,” which determines the FDA component to which a combination product is assigned. We proposed to update these regulations further on May 15, 2018 (83 FR 22428), intending to: (1) Clarify the scope of our regulations; (2) streamline and clarify the appeals process; (3) align the regulations with more recent legislative and regulatory measures; (4) update advisory content; and (5) clarify Agency policies and practices.

We are revising the information collection to include changes to these existing procedures and current statutory and legislative mandates. Specifically, as amended by the Cures Act, section 503(g) of the FD&C Act includes provisions exclusive to FDA’s Office of Combination Products (OCP) and/or to provide for combination product-specific submission types, including provisions addressing engagement between OCP and combination product sponsors and Combination Product Agreement Meetings (CPAMs) for sponsors to engage with FDA. In addition, FDA has developed an associated jurisdictional process to the RFD process, the pre-RFD process, for sponsors to obtain feedback regarding medical product classification and assignment.

To assist respondents with format and content elements related to the information collection for RFDs and pre-

RFDs, we have developed proposed Forms FDA 5003, 5004, and 5005 (pre-request and request for designation). To support RFD and pre-RFD submissions, FDA has also made information technology improvements, enabling sponsors to use preferred submission methods, including automated, electronic, mechanical, and other technological collection techniques. We expect the use of improved technology to enhance sponsors’ user experience with submissions.

We have also developed Agency guidance consistent with sections 503(g) and 563 of the FD&C Act and with our Good Guidance Practice regulations in 21 CFR 10.115 (approved under OMB control number 0910–0191).

The guidance entitled “How to Write a Request for Designation” (issued April 2011), provides instruction regarding the information that needs to be submitted to OCP in a RFD as described in 21 CFR 3.7. The guidance is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-write-request-designation-rfd>. In the **Federal Register** of July 17, 2019 (84 FR 34188), we published a notice requesting public comment on the proposed collection of information associated with 21 CFR part 3; no comments were received.

The guidance entitled “How to Prepare a Pre-Request for Designation,” was developed to assist sponsors in obtaining a preliminary, nonbinding assessment from OCP through the pre-RFD process. The guidance explains the pre-RFD process and helps a sponsor understand the type of information to provide in a pre-RFD submission. The guidance is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-prepare-pre-request-designation-pre-rfd>. In the **Federal Register** of January 13, 2017 (82 FR 4351), we published a notice announcing the availability of the draft guidance that included an analysis under the PRA and solicited public comment on the recommended information collection. In consideration of comments, we made minor edits to the guidance, including clarifying our pledge of confidentiality for information submitted and clarifying that OCP may be contacted at any time to discuss questions. No comments suggested revision to the information collection, and therefore we made no adjustment in our burden estimate.

The guidance entitled “Requesting FDA Feedback on Combination Products,” was developed to discuss ways in which combination product sponsors can obtain feedback from FDA on scientific and regulatory questions