



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0529]

Qualification Process for Drug Development Tools; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) are announcing the availability of a final guidance for industry and FDA staff entitled "Qualification Process for Drug Development Tools." Under the 21st Century Cures Act (Cures Act), enacted on December 13, 2016, a new section was added to the Federal Food, Drug, and Cosmetic Act (FD&C Act), which defined a three-stage qualification process for drug development tools (DDTs). This guidance meets the Cures Act's requirement to issue guidance on this qualification process. It elaborates on the new qualification process and transparency requirements and discusses the taxonomy for biomarkers and other DDTs. This guidance finalizes the draft guidance of the same title issued on December 16, 2019.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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-2010-D-0529 for "Qualification Process for Drug Development Tools." 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; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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: Chris Leptak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6461, Silver Spring, MD 20993-0002, 301-796-0017; or Stephen Ripley, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002; 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

CDER and CBER are announcing the availability of a final guidance for industry and FDA staff entitled “Qualification Process for Drug Development Tools.” Signed into law on December 13, 2016, the Cures Act codified, in new section 507 of the FD&C Act (21 U.S.C. 357), a new statutory process for DDT qualification and added transparency provisions for information related to qualification submissions through which there is enhanced ability to share knowledge. In addition, Congress directed the establishment of a taxonomy for the classification of biomarkers (and related scientific concepts) for use in drug (including biological product) development. CDER and CBER convened a public meeting on December 11, 2018, to solicit public input about implementing the new qualification process under section 507 of the FD&C Act and about identifying the Biomarkers, Endpoints, and other Tools (BEST) glossary as the taxonomy for classifying types of DDTs, including biomarkers. CDER and CBER are issuing this final guidance to meet the Cures Act requirement that the Agency issue final guidance on the section 507 qualification process.

DDTs are methods, materials, or measures that can aid drug development and regulatory review. Qualification means that a DDT and its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review.

Qualified DDTs can accelerate the integration of innovation, clinical knowledge, and scientific advances, thereby expediting drug development and aiding the regulatory review of applications.

Although the DDT qualification process is voluntary, requestors who seek qualification under section 507 of the FD&C Act must follow the three-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.