

project. The project's goal is to create a technically sound and feasible instrument that will provide consistent, systematic measures of the implementation and costs of education and care in center-based settings that serve children from birth to age 5. The resulting measures will inform research, policy, and practice by improving understanding of variations in what

centers do to support quality, their associated costs, and how resources for ECE may be better aligned with expectations for quality. The study received approval for a field test to validate and improve the psychometric properties of these measures in November 2019. For all previously approved materials for this study, see <https://www.reginfo.gov/public/do/>

*PRAOMBHistory?ombControlNumber=0970-0499.* This request is to add a measure to the approved field test to help further assess the associations between measures of implementation, cost, and quality. The field test and this additional measure will include only remote data collection.

*Respondents:* Teachers and aids.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
Center re-engagement call and roster update for teaching staff survey	80	1	.50	40
Teaching staff survey .....	1,120	1	.50	560

*Estimated Total Annual Burden Hours:* 600.

**Authority:** § 658O(a)(5) as amended by the CCDBG Act of 2014 § 9.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2020-D-0420]

**Providing Regulatory Submissions in Alternate Electronic Format; 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 “Providing Regulatory Submissions in Alternate Electronic Format.” Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), Congress granted FDA the authority to implement the statutory electronic submission requirements in guidance. In response, FDA implemented binding guidance requiring that new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain drug master files (DMFs), certain biologics license applications (BLAs), and certain investigational new drug applications (INDs) be submitted to the Agency in electronic common technical document format. Recognizing that some submissions are exempt from this

requirement and that waivers of the requirement may be granted on a case-by-case basis, the Agency is issuing this guidance to provide recommendations on an alternate electronic format for submissions covered under such exemptions and waivers. This guidance replaces the draft guidance of the same title issued on March 11, 2020.

**DATES:** The announcement of the guidance is published in the **Federal Register** on July 2, 2021.

**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-2020-D-0420 for “Providing Regulatory Submissions in Alternate Electronic Format.” 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 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 20993-0002, or to 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:** Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993-0002, 240-402-8926; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

### **I. Background**

FDA is announcing the availability of a guidance for industry entitled

“Providing Regulatory Submissions in Alternate Electronic Format.” This guidance provides recommendations on an alternate electronic format for submissions that are covered under an exemption from or granted a waiver of the requirements of section 745A(a) of the FD&C Act (21 U.S.C. 379k-1). These recommendations pertain to the electronic format of content in NDAs, ANDAs, certain DMFs, certain BLAs, and certain INDs submitted to the Center for Drug Evaluation and Research or to the Center for Biologics Evaluation and Research.

This guidance includes information on: (1) How to submit in alternate electronic format (without XML backbone), (2) submission of FDA forms, (3) pre-submission considerations, (4) submission structure, (5) file formats and versions, (6) datasets and study information, (7) transmitting electronic submissions, and (8) receipt dates.

This guidance finalizes the draft guidance of the same title issued on March 11, 2020 (85 FR 14202). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to final guidance include: (1) Minor edits to clarify recommendations for the location of the Table of Contents for the alternate electronic format, (2) an example of the folder structure, and (3) the process for submission if an electronic signature is not possible. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This final guidance represents FDA’s current thinking on “Providing Regulatory Submissions in Alternate Electronic Format.” 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 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR part 314 have been approved under OMB control

number 0910-0001; and the collections of information 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 <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: June 28, 2021.

**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-2021-N-0008]

### **Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA’s regulatory issues. The meeting will be open to the public.

**DATES:** The meeting will take place virtually on August 3, 2021, from 9 a.m. Eastern Time to 6 p.m. Eastern Time.

**ADDRESSES:** Please note that due to the impact of the COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions, including information regarding special accommodations due to a disability, may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

**FOR FURTHER INFORMATION CONTACT:** Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 66, Rm. 5214, Silver Spring, MD 20993-0002,