products must also typically conduct comparative testing requiring access to brand product samples.

Under the CREATES Act, the product developer must take several specific steps (outlined in the CREATES Act) before the brand company is required to sell them product samples. If the brand product for which samples are sought is subject to a REMS with ETASU, the product developer must first obtain a CPA from FDA (21 U.S.C. 355–2(b)(2)). (CPAs are only available for products that are subject to a REMS with ETASU. To prevail in the private right of action established by CREATES, an eligible product developer seeking samples of a product that is *not* subject to a REMS with ETASU does not need to obtain a CPA.)

This information collection enables eligible product developers to obtain CPAs from FDA so that they can utilize the pathway made available by the CREATES Act. An ANDA, 505(b)(2), or biosimilar product developer's use of the CREATES pathway is voluntary, as is the product developer's request for a CPA. Accordingly, under this information collection, FDA will collect information voluntarily provided by eligible product developers in the form of requests for CPAs and supporting documentation. Requests for CPAs for samples of brand products used for purposes of development and testing that involve human clinical trials should be accompanied by study protocols, informed consent documents, and informational materials for testing demonstrating that safety protections comparable to those in the REMS for the brand product will be provided for in the study(ies) for which the samples are sought.

For generic drug products, a request for a CPA is submitted through the CDER NextGen collaboration Portal as complex controlled correspondence to an ANDA. For 505(b)(2) applications and biosimilar applications, the request for a CPA is submitted to the pre-investigational new drug application (pIND) or investigational new drug application (IND) file, and a copy is sent to any existing marketing application for the product and to *ONDCommunications@fda.hhs.gov.*

Respondents for this information collection are drug and biological product developers that are seeking to use the CREATES pathway to obtain samples of brand products needed to support their applications.

For ANDA, 505(b)(2), and biosimilar products, the burden of requesting a CPA is being added to OMB Control No. 0910–0014.

Based on prior experience, FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance Section IV.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
CPA Requests for NDA/Biologics License Application products	1	1	1	5	5
CPA Requests for ANDA products	11	2	22	5	110
Total					115

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20523 Filed 9–21–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0872]

Electronic Submission Template for Medical Device 510(k) Submissions; Guidance for Industry and Food and Drug Administration Staff; 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 entitled ''Electronic Submission Template for Medical Device 510(k) Submissions.'' This final guidance is intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process. This guidance document provides further standards for the submission of 510(k)s by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements.

DATES: The announcement of the guidance is published in the **Federal Register** on September 22, 2022.

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–2021–D–0872 for ''Electronic Submission Template for Medical Device 510(k) Submissions.'' 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 § 10.115(g)(5) (21 CFR 10.115(g)(5))).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Electronic Submission Template for Medical Device 510(k) Submissions'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993–0002, 301–796–6527; 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, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k–1(b)), amended by section 207 of the FDA Reauthorization Act of 2017 (Pub. L. 115–52), requires that presubmissions and submissions for devices under section 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f), 520(g), 520(m), or 564 of the FD&C Act (21 U.S.C. 360(k), 360c(f)(2)(A), 360e(c), 360e(d), 360e(f), 360j(g), 360j(m), or 360bbb–3) or section 351 of the Public Health Service Act (42 U.S.C. 262) and any supplements to such presubmissions or submissions, including appeals of those submissions, be submitted in electronic format specified by FDA beginning on such date as specified by FDA in final guidance. It also mandates that FDA issue a draft guidance not later than October 1, 2019, providing for further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements.

In addition, in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter [1] from the Secretary of Health and Human Services to Congress, FDA committed to developing ''electronic submission templates that will serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process'' and ''[b]y FY [fiscal year] 2020, the Agency will issue a draft guidance document on the use of the electronic submission templates.'' In addition, the Commitment Letter states that ''[n]o later than 12 months after the close of the public comment period, the Agency will issue a final guidance.'' FDA's guidance document ''Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act'' issued July 15, 2020, (the ''parent guidance'') [2] was intended to satisfy the final guidance documents referenced in section 745A(b)(3) of the FD&C Act and the MDUFA IV Commitment Letter. A notice of availability of the parent guidance appeared in the **Federal Register** of July 15, 2020 (85 FR 42864).

In the parent guidance, the Agency concluded that it is not feasible to describe and implement the electronic format(s) that would apply to all the submissions covered by section 745A(b) of the FD&C Act in one guidance document. Accordingly, the parent guidance describes how FDA interprets and plans to implement the requirements of section 745A(b)(3) of the FD&C Act, while individual guidances will be developed to specify the formats for specific submissions and corresponding timetables for implementation.

This final guidance ''Electronic Submission Template for Medical Device 510(k) Submissions'' is the first of these individual guidances that provides further standards for the submission of 510(k)s by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements. At this time, the electronic Submission Template And

[1] Available at: *https://www.fda.gov/media/102699/download.*

[2] ''Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab.*

Resource (eSTAR) is the only electronic submission template available to prepare a complete 510(k) electronic submission using the guided prompts for the collection of structured and unstructured data.

All 510(k) submissions, including original submissions for Traditional, Special, and Abbreviated 510(k)s, and subsequent Supplements and Amendments (amendments include add-to-files and appeals), and any other subsequent submissions to an original submission unless exempted in this final guidance, will be required to be submitted as electronic submissions as specified in the guidance. Section 745A(b)(2) of the FD&C Act allows for FDA to set forth criteria for exemptions and waivers from electronic submission requirements. FDA has identified such criteria in the final guidance document. FDA is identifying October 1, 2023, as the date on which the 510(k) electronic submission requirements will take effect.

A notice of availability of the draft guidance appeared in the **Federal Register** of September 29, 2021 (86 FR 53965). FDA considered comments received and revised the guidance as appropriate in response to the comments, including updated criteria for exemptions; clarification of the technical screening hold; and description of the transition period and effective date on which 510(k) electronic submissions will be required.

In section 745A(b) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the statutory requirement for electronic submissions solely in electronic format by providing standards, a timetable, and criteria for waivers and exemptions. To the extent that this final guidance provides such requirements under section 745A(b)(3) of the FD&C Act (*i.e.,* standards, timetable, criteria for waivers of and exemptions), indicated by the use of the mandatory words, such as must or required, this document is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. (See § 10.115(d).)

To the extent that this final guidance describes recommendations that are not standards, timetable, criteria for waivers of, or exemptions under section 745A(b)(3) of the FD&C Act, it is being issued in accordance with FDA's good guidance practices regulation (§ 10.115). This guidance represents the current thinking of FDA on this topic. 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. This final guidance contains both binding and nonbinding provisions.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Electronic Submission Template for Medical Device 510(k) Submissions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 19006 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new 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 the following FDA regulations and forms have been approved by OMB as listed in the following table:

21 CFR part or FDA form	Topic	OMB control No.
807 subpart E, including forms FDA 4062 eSTAR and FDA 4078 eSTAR (for In Vitro Diagnostic (IVD) 510(k) submissions).	Premarket Notification Submission, including submissions via eSTAR.	0910–0120
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

Dated: September 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20512 Filed 9–21–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: HRSA Ryan White HIV/AIDS Program HIV Quality Measures Module, OMB No. 0906–0022—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than October 24, 2022.

ADDRESSES: Written comments and recommendations for the proposed