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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–7945.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Over-the-Counter Monograph Submissions in Electronic Format.'' This guidance provides information on providing electronic submissions to FDA under section 505G of the FD&C Act (21 U.S.C. 355h) (hereafter referred to as over-the-counter (OTC) monograph submissions). This guidance is intended to assist submitters by describing the electronic OTC monograph submissions requirement in section 505G(j) of the FD&C Act and providing recommendations and other information on how to send such OTC monograph submissions to FDA in electronic format.

Section 505G of the FD&C Act was added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116–136, which was enacted on March 27, 2020. Section 505G(j) of the FD&C Act requires that all OTC monograph submissions must be in electronic format. As required by section 505G(l)(3) of the FD&C Act, this draft guidance, when finalized, specifies the format of electronic submissions under section 505G of the FD&C Act.

In support of the CARES Act, FDA agreed to specific performance goals and procedures described in the document entitled ''Over-the-Counter Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2018–2022,'' commonly referred to as the OMUFA commitment letter (the document can be accessed at *https://www.fda.gov/media/106407/download* and the document with updated goal dates for fiscal years 2021 to 2025 can be accessed at *https://www.fda.gov/media/146283/download*). In the OMUFA commitment letter, FDA committed to issuing this draft guidance under specific timelines.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Providing Over-the-Counter Monograph Submissions in Electronic Format.''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

Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 does not apply to collections of information made under section 505G of the FD&C Act. This guidance is being issued to implement the provisions of section 505G(l)(3) of the FD&C Act, which specifies the format of electronic submissions to FDA under section 505G of the FD&C Act. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain 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 23, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21007 Filed 9–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0987]

Policy for Coronavirus Disease—2019 Tests During the Public Health Emergency (Revised); Immediately in Effect Guidance for Commercial Manufacturers 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 document related to the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE) entitled ''Policy for Coronavirus Disease—2019 Tests During the Public Health Emergency (Revised).'' FDA is issuing this guidance to provide FDA's revised enforcement policies and review priorities regarding certain novel coronavirus (COVID–19) tests for the duration of the public health emergency. Rapid detection of COVID–19 cases in the United States requires wide availability of testing to control the spread of this highly contagious infection. This document supersedes ''Policy for Coronavirus Disease—2019 Tests During the Public Health Emergency (Revised)'' issued November 15, 2021. The guidance identified in this notice addresses issues related to the COVID–19 PHE and has been issued in accordance with the expedited process FDA announced in the **Federal Register** of March 25, 2020, for making available to the public COVID–19-related guidances. This guidance has been implemented without prior comment, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on September 28, 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–2020–D–0987 for ''Policy for Coronavirus Disease—2019 Tests During the Public Health Emergency (Revised).'' 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))).

Submit written requests for a single hard copy of the guidance document entitled ''Policy for Coronavirus Disease—2019 Tests During the Public Health Emergency (Revised)'' 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Toby Lowe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3416, Silver Spring, MD 20993–0002, 301–796–6512.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance entitled ''Policy for Coronavirus Disease—2019 Tests During the Public Health Emergency (Revised),'' which supersedes the guidance of the same title issued November 15, 2021. FDA is issuing this guidance to provide FDA's updated enforcement policies and review priorities regarding certain novel coronavirus (COVID–19) tests for the duration of the public health emergency. Rapid detection of COVID–19 cases in the United States requires wide availability of testing to control the spread of this highly contagious infection.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3), the FDA Commissioner may authorize the use of unapproved medical products, or unapproved uses of approved medical products, in certain emergency circumstances, after the HHS Secretary has made a declaration of emergency or threat justifying authorization of emergency use, to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological, and nuclear threat agents when certain criteria are met (emergency use authorization (EUA)). As of August 15, 2022, FDA has authorized under EUA more than 439 tests for COVID–19, including more than 354 diagnostic and 85 serology or other immune response tests. Further, two molecular diagnostic COVID–19 tests have been granted marketing authorization through the traditional device premarket review pathways.

In the context of a public health emergency involving pandemic infectious disease, it is critically important that tests are validated because false results not only can negatively impact the individual patient but also can have a broad public health impact. False positive results for diagnostic tests, for example, can lead to unnecessary quarantine and potential further spread when presumed positive individuals are quarantined together, wasted contact tracing and testing resources, and delay in accurate diagnosis and appropriate treatment for the individual. False negative results can lead to lack of appropriate treatment for the individual and further spread of the disease.

FDA has continued to closely monitor the COVID–19 testing landscape and believes it is appropriate to update its policies to reflect the current needs of the pandemic. As explained throughout this updated guidance, FDA intends to review the EUA requests for a smaller subset of tests. Traditional marketing pathways remain available to all developers and FDA encourages developers of tests that fall outside the scope of the priorities outlined in this updated guidance to pursue those routes. In sum, FDA has revised this guidance to update the types of COVID–19 tests for which the Agency intends to review EUA requests, to discuss the use of the traditional premarket review pathways for other types of COVID–19 tests for which the Agency does not intend to review EUA requests, and to make minor updates to the enforcement policies.

On January 31, 2020, as a result of confirmed cases of COVID–19, and after consultation with public health officials as necessary, the Secretary of Health and Human Services (HHS), pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247d), determined that a PHE exists and has existed since January 27, 2020, nationwide.[1] On March 13, 2020, there was a Presidential declaration that the COVID–19 outbreak in the United States constitutes a national emergency, beginning March 1, 2020.[2]

[1] Secretary of Health and Human Services, ''Determination that a Public Health Emergency Exists'' (originally issued on January 31, 2020, and subsequently renewed), available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx*.

[2] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak (March 13, 2020), available at: *https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-*

In the **Federal Register** of March 25, 2020 (85 FR 16949) (the March 25, 2020, notice) (available at *https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf*), FDA announced various procedures for making available FDA guidances related to the COVID–19 PHE. The March 25, 2020, notice stated that due to the need to act quickly and efficiently to respond to the COVID–19 PHE and to allow FDA to rapidly disseminate Agency recommendations and policies related to COVID–19 to industry, FDA staff, and other stakeholders, prior public participation would not be feasible or appropriate before FDA implemented COVID–19-related guidances. FDA will continue to issue COVID–19-related guidances for immediate implementation without prior public comment (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and § 10.115(g)(2)). The guidances are available on FDA's web pages entitled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders'' (available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders*) and ''Search for FDA Guidance Documents'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*.) Although this guidance has been implemented immediately without prior comment, FDA will consider all comments received and revise the guidance as appropriate (see § 10.115(g)(3)).

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA. 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

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA). The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the table below. This guidance also contains a new collection of information not approved under a current collection. The new collection of information has been granted a public health emergency (PHE) waiver from the PRA by the Department of Health and Human Services (HHS) on March 19, 2020, under section 319(f) of the PHS Act. Information concerning the PHE PRA waiver can be found on the HHS website at *https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers*.

21 CFR part or guidance	Topic	OMB control No.	New collection covered by PHE PRA waiver
Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders.	Emergency Use Authorization	0910–0595	
''Administrative Procedures for CLIA Categorization; Guidance for Industry and Food and Drug Administration Staff'' and ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices; Guidance for Industry and Food and Drug Administration Staff''.	Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization.	0910–0607	
803	Medical devices; medical device reporting; manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437	
807, subpart E	Premarket notification	0910–0120	
814, subparts A through E	Premarket approval	0910–0231	
860, subpart D	De Novo classification process	0910–0844	
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions; pre-submissions	0910–0756	
			Voluntary templates to facilitate the preparation and submission of an Emergency Use Authorization request for various types of COVID–19 tests.

III. Electronic Access

Persons with access to the internet may obtain the guidance at:

- FDA web page entitled ''Guidance Documents (Medical Devices and Radiation-Emitting Products)'' available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products*;
- FDA web page entitled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-*

disease-covid-19-outbreak/. On February 24, 2021, there was a Presidential Declaration continuing the national emergency concerning the COVID–19 pandemic beyond March 1, 2021. See Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID–19) Pandemic (February 24, 2021), available at *https://www.federalregister.gov/documents/2021/02/26/2021-04173/continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic*.

related-guidance-documents-industry-fda-staff-and-other-stakeholders;

- FDA web page entitled ''Search for FDA Guidance Documents'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*; or
- *https://www.regulations.gov*.

Dated: September 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20828 Filed 9–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA), Center for Biologics Evaluation and Research (CBER), Office of Tissues and Advanced Therapies (OTAT) has modified its organizational structures.

DATES: These new organizational structures were approved by the Secretary of Health and Human Services on August 8, 2022, and effective on September 16, 2022.

FOR FURTHER INFORMATION CONTACT: Yashika Rahaman, Director, Office of Planning, Evaluation and Risk Management, Office of Finance, Budget, Acquisitions and Planning, FDA, 4041 Powder Mill Road, Beltsville, MD, 20705–4304, 301–796–3843.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is revised to reflect the Food and Drug Administration's reorganization of CBER, Office of Tissues and Advanced Therapies (OTAT).

CBER's mission is to protect and enhance public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. With substantial growth in innovative, novel products, as well as a need to address an ever-changing landscape of potential public health threats, CBER is currently facing scientific, medical, and regulatory challenges that require changes to its structure.

Utilizing key tenets of CBER's modernization efforts, CBER will retitle OTAT to the Office of Therapeutic Products (OTP) and elevate OTP to a Super Office to manage its program at a macro level and to better position the Center to address an everchanging public health landscape. With the current and anticipated increase in workloads, the proposed structural changes will improve functional alignment, increase review capabilities, and enhance expertise on new cell and gene therapies. Additional supervisory positions will not only help to address this increased workload but will also provide advancement opportunities to facilitate recruitment and retention of highly qualified staff. The proposal creates flexibility and capacity for future growth in Full-Time Employees (FTEs) and workload, avoiding the need for continual reorganizations. The reorganization will position OTP to focus on commitments, including those negotiated with industry in the prescription drug user fee agreement (PDUFA) for FY 2023–2027, and other key priorities that protect public health. To advance the field and support the next generation of cell and gene therapies, OTP will continue to see growth in the Regenerative Medicine Advanced Therapy (RMAT) program, established in the 21st Century Cures Act.

The Food and Drug Administration's Center for Biologics Evaluation and Research, Office of Tissues and Advanced Therapies, has been restructured as follows:

DCB. ORGANIZATION. The Center for Biologics Evaluation and Research is headed by the Center Director, Center for Biologics Evaluation and Research.

Center for Biologics Evaluation and Research (DCB)

Office of Therapeutic Products (DCBG)
Administrative Staff (DCBG1)
Policy and Special Projects Staff (DCBG2)
Office of Gene Therapy CMC (DCBGF)
Division of Gene Therapy I (DCBGFA)
Gene Therapy Branch 1 (DCBGFA1)
Gene Therapy Branch 2 (DCBGFA2)
Gene Therapy Branch 3 (DCBGFA3)
Division of Gene Therapy II (DCBGFB)
Gene Transfer and Immunogenicity Branch (DCBGFB1)
Gene Therapy Branch 4 (DCBGFB2)
Gene Therapy Branch 5 (DCBGFB3)
Office of Cellular Therapy and Human Tissues CMC (DCBGG)
Division of Cell Therapy I (DCBGGA)
Cell Therapy Branch 1 (DCBGGA1)
Cell Therapy Branch 2 (DCBGGA2)
Cellular and Tissue Therapy Branch (DCBGGA3)
Division of Cell Therapy II (DCBGGB)
Tissue Engineering Branch 1 (DCBGGB1)
Tissue Engineering Branch 2 (DCBGGB2)
Tumor Vaccine and Biotechnology Branch (DCBGGB3)
Division of Human Tissues (DCBGGC)
Human Tissues and Reproduction Staff (DCBGGC1)
Office of Plasma Protein Therapeutics CMC (DCBGH)
Division of Hemostasis (DCBGHA)
Hemostasis Branch 1 (DCBGHA1)
Hemostasis Branch 2 (DCBGHA2)
Division of Plasma Derivatives (DCBGHB)
Plasma Derivatives Branch 1 (DCBGHB1)
Plasma Derivatives Branch 2 (DCBGHB2)
Office of Clinical Evaluation (DCBGI)
Division of Clinical Evaluation General Medicine (DCBGIA)
General Medicine Branch 1 (DCBGIA1)
General Medicine Branch 2 (DCBGIA2)
General Medicine Branch 3 (DCBGIA3)
General Medicine Branch 4 (DCBGIA4)
Division of Clinical Evaluation Oncology (DCBGIB)
Oncology Branch 1 (DCBGIB1)
Oncology Branch 2 (DCBGIB2)
Division of Clinical Evaluation Hematology (DCBGIC)
Benign Hematology Branch (DCBGIC1)
Malignant Hematology Branch (DCBGIC2)
Office of Pharmacology/Toxicology (DCBGJ)
Division of Pharmacology/Toxicology I (DCBGJA)
Pharmacology/Toxicology Branch 1 (DCBGJA1)
Pharmacology/Toxicology Branch 3 (DCBGJA2)
Division of Pharmacology/Toxicology II (DCBGJB)
Pharmacology/Toxicology Branch 2 (DCBGJB1)
Pharmacology/Toxicology Branch 4 (DCBGJB2)
Office of Review Management and Regulatory Review (DCBGK)
Division of Review Management and Regulatory Review I (DCBGKA)
Regulatory Review Branch 1 (DCBGKA1)
Review Management Support Branch 1 (DCBGKA2)
Division of Review Management and Regulatory Review II (DCBGKB)