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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2020-D-0987, FDA-2020-D-1106, FDA-2020-D-1136, FDA-2020-D-1137, FDA-2020-D-1825]

Guidance Documents Related to Coronavirus Disease 2019; 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 FDA guidance documents related to the Coronavirus Disease 2019 (COVID-19) public health emergency (PHE). This notice of availability (NOA) is pursuant to the process that FDA announced, in the *Federal Register* of March 25, 2020, for making available to the public COVID-19-related guidances. The guidances identified in this notice address issues related to the COVID-19 PHE and have been issued in accordance with the process announced in the March 25, 2020, notice. The guidances have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidances 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 name of the guidance document that the comments address and the docket number for the guidance (see table 1). Received comments will be placed in the docket(s) 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 single copies of these guidances to the address noted in table 1. Send two self-addressed adhesive labels to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911, Kimberly Thomas, Center

for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6220, Silver Spring, MD 20993-0002, 301-796-2357, or Erica Takai, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993-0002, 301-796-6353.

SUPPLEMENTARY INFORMATION:

I. Background

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]

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 procedures for making available FDA guidances related to the COVID-19 PHE. These procedures, which operate within FDA's established good guidance practices regulations, are intended to allow FDA to rapidly disseminate Agency recommendations and policies related to COVID-19 to industry, FDA staff, and other stakeholders. The March 25, 2020, notice stated that due to the need to act quickly and efficiently to respond to the COVID-19 PHE, FDA believes that prior public participation will not be feasible or appropriate before FDA

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[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-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.

implements COVID-19-related guidances. Therefore, FDA will issue COVID-19-related guidances for immediate implementation without prior public comment (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic 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).

The March 25, 2020, notice further stated that, in general, rather than publishing a separate NOA for each COVID-19-related guidance, FDA intends to publish periodically a consolidated NOA announcing the availability of certain COVID-19-related guidances that FDA issued during the relevant period, as included in table 1. This notice announces COVID-19-related guidances that are posted on FDA's website.

II. Availability of COVID-19-Related Guidance Documents

Pursuant to the process described in the March 25, 2020, notice, FDA is announcing the availability of the following COVID-19-related guidances:

Table 1.--Guidances Related to the COVID-19 Public Health Emergency

Docket No.	Center	Title of Guidance	Contact Information to Request Single Copies
FDA-2020-D-1825	CBER	Investigational COVID-19 Convalescent Plasma (Updated February 2021)	Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, 1-800-835-4709 or 240-402-8010; email ocod@fda.hhs.gov.
FDA-2020-D-1137	CBER	Emergency Use Authorization for Vaccines to Prevent COVID-19 (Updated February 2021)	Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, 1-800-835-4709 or 240-402-8010; email ocod@fda.hhs.gov.
FDA-2020-D-1136	CDER	COVID-19 Container Closure System and Component Changes: Glass Vials and Stoppers Guidance for Industry (March 2021)	druginfo@fda.hhs.gov. Please include the docket number FDA-2020-D-1136 and complete title of the guidance in the request.

FDA-2020-D-1136	CDER	Development of Monoclonal Antibody Products Targeting SARS-CoV-2, Including Addressing the Impact of Emerging Variants, During the COVID 19 Public Health Emergency (February 2021)	druginfo@fda.hhs.gov. Please include the docket number FDA-2020-D-1136 and complete title of the guidance in the request.
FDA-2020-D-1106	CDER	Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) (Updated February 2021)	druginfo@fda.hhs.gov. Please include the docket number FDA-2020-D-1106 and complete title of the guidance in the request.
FDA-2020-D-1106	CDER	Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) (Updated February 2021)	druginfo@fda.hhs.gov. Please include the docket number FDA-2020-D-1106 and complete title of the guidance in the request.
FDA-2020-D-0987	CDRH	Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests (February 2021)	CDRH-Guidance@fda.hhs.gov. Please include the document number 21104 and complete title of the guidance in the request.

Although these guidances have been implemented immediately without prior comment, FDA will consider all comments received and revise the guidances as appropriate (see § 10.115(g)(3)).

These guidances are being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidances represent the current thinking of FDA. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

A. CBER Guidances

While these guidances contain no collection of information, they do refer to previously approved FDA collections of information (listed in table 2). 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 these guidances. 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 guidances have been approved by OMB as listed in the following table:

Table 2.--CBER Guidances and Collections

COVID-19 Guidance Title	CFR Cite Referenced in COVID-19 Guidance	Another Guidance Title Referenced in COVID-19 Guidance	OMB Control No(s).
Emergency Use Authorization for Vaccines to Prevent COVID-19 (Updated: February 22, 2021)	21 CFR 314.420 21 CFR part 312 21 CFR parts 210, 211, and 610 21 CFR part 600 21 CFR part 601	Emergency Use Authorization of Medical Products and Related Authorities	0910-0001 0910-0014 0910-0139 0910-0308 0910-0338 0910-0595
Investigational COVID-19 Convalescent Plasma; Guidance for Industry (Updated: February 11, 2021)	21 CFR part 312 21 CFR parts 606 and 630	Form FDA 3926	0910-0014 0910-0116 0910-0814

B. CDER Guidances

While these guidances contain no collection of information, they do refer to previously approved FDA collections of information (listed in table 3). Therefore, clearance by OMB under the PRA (44 U.S.C. 3501-3521) is not required for these guidances. 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 guidances have been approved by OMB as listed in the following table:

Table 3.--CDER Guidances and Collections

COVID-19 Guidance Title	CFR Cite Referenced in COVID-19 Guidance	Another Guidance Title referenced in COVID-19 Guidance	OMB Control Nos.
COVID-19 Container Closure System and Component Changes: Glass Vials and Stoppers Guidance for Industry (March 2021)	21 CFR 314.70 21 CFR 314.97 21 CFR 601.12 21 CFR 314.420	Requests for Expedited Review of New Drug Application and Biologics License Application Prior Approval Supplements Submitted for Chemistry, Manufacturing, and Controls Changes Comparability Protocols for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information (April 2016) Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products (December 2017) Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products (July 1997) Changes to an Approved NDA or ANDA (April 2004)	0910-0001 0910-0338 0910-0139

		Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation (May 1999) CMC Postapproval Manufacturing Changes for Specified Biological Products To Be Documented in Annual Reports (August 2017) Comparability Protocols for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information (April 2016) Drug Master Files (October 2019) Harmonizing Compendial Standards With Drug Application Approval Using the USP Pending Monograph Process (July 2019) Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency; Questions and Answers (August 2020) PAC-ATLS: Postapproval Changes--Analytical Testing Laboratory Sites (April 1998) Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products (November 1994) Immediate Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation (November 1995) Nonsterile Semisolid Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation (May 1997) SUPAC: Manufacturing Equipment Addendum (December 2014) SUPAC-IR: Questions and Answers about SUPAC-IR Guidance (February 1997) SUPAC-MR: Modified Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation (September 1997) Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug	

		Substances and New Drug Products: Chemical Substances (December 2000) Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products (August 1999) Q9 Quality Risk Management (June 2006) Q10 Pharmaceutical Quality System (April 2009)	
Development of Monoclonal Antibody Products Targeting SARS-CoV-2, Including Addressing the Impact of Emerging Variants, During the COVID-19 Public Health Emergency (February 2021)	21 CFR 312 21 CFR 601.20	Emergency Use Authorization of Medical Products and Related Authorities (January 2017) COVID-19: Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS-CoV-2 Infectivity (January 2021) S6(R1) Preclinical Safety Evaluation of Biotechnology-Delivered Pharmaceuticals (May 2012) CGMP for Phase 1 Investigational Drugs (July 2008). COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (February 1997). COVID-19: Developing Drugs and Biological Products for Treatment or Prevention (February 2021) Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency (June 2006)	0910-0014 0910-0001 0910-0338 0910-0139

Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) (Updated February 10, 2021)		Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Adverse Event Reporting Requirements Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID-19) Q3C Guideline on Impurities: Guideline for Residual Solvents	0910-0045 0910-0139 0910-0230 0910-0291 0910-0340 0910-0641 0910-0645 0910-0800
Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) (Updated February 10, 2021)	21 CFR 207.17 21 CFR 207.25 21 CFR 207.41	Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID-19) Q3C Guideline on Impurities: Guideline for Residual Solvents	0910-0045 0910-0139 0910-0230 0910-0291 0910-0340 0910-0641

C. CDRH Guidance

While this guidance contains no collection of information, it does refer to a previously approved FDA collection of information (listed in table 4). Therefore, clearance by OMB under the PRA (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collection of information is subject to review by OMB under the PRA. The collection of information in the following FDA guidance has been approved by OMB as listed in the following table:

Table 4.--CDRH Guidance and Collections

COVID-19 Guidance Title	CFR Cite Referenced in COVID-19 Guidance	Another Guidance Title Referenced in COVID-19 Guidance	OMB Control No(s).
Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests (February 2021)		Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders	0910-0595

IV. Electronic Access

Persons with access to the internet may obtain COVID-19-related guidances at:

- 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-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: April 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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