FD&C Act. The regulations provide instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection, for which a hearing has been requested, must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under 21 CFR 12.24 and does not limit the evidence that may be presented if a hearing is granted. We estimate five respondents will file a request under the regulation and assume each request requires 20 hours to prepare, for a total of 100 hours annually.

Finally, § 12.45 (21 CFR 12.45), issued under section 701 of the FD&C Act, sets forth content, format, and procedural requirements for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, concerning disclosure of data and information by participants (21 CFR 13.25). In accordance with § 12.45(e), the presiding officer may omit a participant's appearance. Based on our records, we estimate five filings under this regulation and assume it requires 3 hours to prepare, for a total of 15 hours annually.

Respondents to the information collection are those interested persons conducting business with FDA, and thus subject to the applicable administrative regulations.

The burden estimates for this collection of information are based on Agency records and our experience over the past 3 years. By revising the information collection to include additional provisions, we have increased our annual burden estimate by 869 responses and 1,096 hours.

Dated: May 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10384 Filed 5–14–20; 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; Immediately in Effect Guidance for Clinical Laboratories, 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 entitled ''Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency.'' On February 4, 2020, the Secretary of Health and Human Services (HHS) determined that there is a public health emergency and that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV). Rapid detection of Coronavirus Disease-2019 (COVID–19) cases in the United States requires wide availability of SARS-CoV–2 testing. This guidance was revised on March 16, 2020, May 4, 2020, and May 11, 2020. The guidance describes four policies intended to help facilitate the development and use of SARS-CoV–2 tests during the public health emergency: Two policies for accelerating the development of certain laboratory tests for COVID–19—one leading to an Emergency Use Authorization (EUA) submission to FDA and the other not leading to an EUA submission when the test is developed under the authorities of the State in which the laboratory resides and the State takes responsibility for COVID–19 testing by laboratories in its State; a policy for commercial manufacturers to more rapidly distribute their SARS-CoV–2 diagnostics to laboratories for specimen testing after validation while an EUA submission is being prepared for submission to FDA; and a policy regarding the use of serological testing. In addition, FDA has included a reference to the availability, on FDA's website, of templates for commercial manufacturers and laboratories intended to facilitate EUA submissions for molecular, antigen, and serology tests. The guidance document is immediately in effect, 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 May 15, 2020.

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.'' 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.

- 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.

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 ''Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency'' to the Office of Policy, Guidance and Policy Development, 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: Brittany Schuck, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3556, Silver Spring, MD 20993–0002, 301–796–5199.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency.'' On February 4, 2020, the Secretary of HHS determined that there is a public health emergency and that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV).[1] Rapid detection of COVID–19 cases in the United States requires wide availability of SARS-CoV–2 testing. This guidance was originally published on February 29, 2020, to describe a policy regarding laboratories using tests they develop and validate before FDA has issued an EUA for their test in order to achieve more rapid testing capacity in the United States. The guidance was subsequently updated on March 16, 2020, to include a policy enabling States to take responsibility for oversight of laboratory developed tests within their States, a policy for commercial manufacturers to more rapidly distribute their SARS-CoV–2 diagnostic tests to laboratories for specimen testing after validation while an EUA is being prepared for submission to FDA, and a policy regarding the use of serological testing without an EUA. The guidance was then updated on May 4, 2020, to revise the policy regarding SARS-CoV–2 serology tests as it pertains to commercial manufacturers. Among other things, the updated guidance explained that commercial manufacturers should submit an EUA for their distributed serology tests within 10 business days of notification to FDA of validation or publication of the guidance published on May 4, 2020, whichever is later. The current version of the guidance was posted on May 11, 2020.

This guidance does not change the policies in the May 4, 2020, guidance but includes a new section that references the availability, on FDA's website, of templates for commercial manufacturers and laboratories intended to facilitate EUA submissions for molecular, antigen, and serology tests. The templates provide information and recommendations, and FDA plans to update them as appropriate as we learn more about the COVID–19 disease and gain experience with the EUA process for the various types of COVID–19 tests.

In the context of a public health emergency involving pandemic infectious disease, it is critically important that tests are validated because false results can have a broad public health impact beyond that to the individual patient. In this guidance, FDA provides recommendations regarding validation of COVID–19 tests, which remain unchanged from the guidance published on May 4, 2020. FDA encourages test developers to discuss any alternative approaches to validation with FDA.

In light of this public health emergency,[2] FDA has determined that prior public participation for this guidance is not feasible or appropriate and is issuing this guidance without prior public comment (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i)) and § 10.115(g)(2)). Although this guidance is immediately in effect, FDA will consider all comments received and revise the guidance document as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA on ''Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency.'' 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.

III. 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* and at

[1] *https://www.fda.gov/media/135010/download;.*

[2] Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists. (January 31, 2020, renewed April 21, 2020), available at *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders. Persons unable to download an electronic copy of ''Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency; Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff '' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 20010–R3 and complete title to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the below table. This guidance also contains a new collection of information not approved under a current collection. This new collection of information has been granted a public health emergency (PHE) waiver from the PRA by the Department of HHS on March 19, 2020, under section 319(f) of the Public Health Services 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.*

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance referenced in COVID–19 guidance	OMB Control No(s).	New collection covered by PHE PRA waiver
Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency.	.....	Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders.	0910–0595	
		Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization.	0910–0607	
		De Novo Classification Process (Evaluation of Automatic Class III Designation).	0910–0844	
	803		0910–0437	
	807, subparts A through D.		0910–0625	
	807, subpart E		0910–0120	
	820		0910–0073	
				Laboratory voluntary reporting to FDA of testing capacity information.
				Manufacturer voluntary reporting to FDA of testing capacity information and the number of laboratories in the U.S. with the required platforms installed.
				Laboratory voluntary reporting to FDA of validation data, when validating through a bridging study and not pursuing an EUA for the modification.
				State or territory voluntary notification to FDA of decision to authorize laboratories within that State or territory to develop and perform a test for COVID–19 under authority of its own State law.
				Laboratory voluntary notification to FDA that they have started clinical testing and voluntary reporting of testing capacity information, when the laboratory is authorized to develop and perform a test for COVID–19 under authority of a State or territory.

Dated: May 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10492 Filed 5–14–20; 8:45 am]

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