4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2020-D-1136, FDA-2020-D-1137, FDA-2020-D-1138, FDA-2020-D-1139, FDA-2020-D-1140, FDA-2020-D-1141, FDA-2020-D-1142, and FDA-2020-D-1143]

Process for Making Available Guidance Documents Related to Coronavirus Disease 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the process for making available FDA guidance documents related to the Coronavirus Disease 2019 (COVID-19) public health emergency. FDA believes that this process will allow the Agency to rapidly disseminate essential Agency recommendations and policies related to COVID-19 to industry, FDA staff, and other stakeholders.

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240-402-5692; May Nelson, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4420, Silver Spring, MD 20993-0002, 301-796-9241; John Weiner, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5130; Silver Spring, MD 20993-0002, 301-796-8941; or Erik Mettler, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., ELEM Rm. 3008, Rockville, MD 20857, 301-796-9254.

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, Alex M. Azar II, Secretary of Health and Human Services, pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247), determined that a public health emergency exists and has existed since January 27, 2020, nationwide.[1] On March 13, 2020, President Donald J. Trump declared that the COVID-19 outbreak in the United States constitutes a national emergency, beginning March 1, 2020.[2] FDA is committed to providing timely recommendations, regulatory advice, guidance, and technical assistance on an Agency-wide basis on issues related to COVID-19, including to clarify our expectations regarding regulatory requirements to support response efforts to this emergency. To this end, FDA is announcing procedures for making available FDA guidance documents related to the COVID-19 public health emergency. FDA believes that these procedures, which operate within FDA's established good guidance practices regulations, will allow the Agency to

[1] Determination that a Public Health Emergency Exists (January 31, 2020), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

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

rapidly disseminate Agency recommendations and policies related to COVID-19 to industry, FDA staff, and other stakeholders.

II. Procedures for Making COVID-19-Related Guidance Documents Available

To facilitate issuance of guidance on topics related to the COVID-19 public health emergency, the Agency intends to use the following procedures:

- In light of the need to act quickly and efficiently to respond to the COVID-19 public health emergency, FDA anticipates that prior public participation will not be feasible or appropriate before FDA implements COVID-19-related guidance documents. FDA anticipates it will issue COVID-19-related guidance documents 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 21 CFR 10.115(g)(2) (§ 10.115(g)(2)).
- Although FDA expects that COVID-19-related guidances will be implemented without prior comment, FDA will solicit comment, review all comments received, and revise the guidance documents as appropriate (see § 10.115(g)(2)). Each guidance will specify the docket number(s) to which comments can be submitted.
- Guidance documents related to COVID-19 will be accessible on the internet from the FDA webpage entitled "Coronavirus Disease 2019 (COVID-19)," available at https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19.
- Guidance documents related to COVID-19 may also be accessed from the FDA webpage entitled "Search for FDA Guidance Documents" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

- Rather than publishing a separate Notice of Availability (NOA) for each COVID-19-related guidance document, FDA intends to publish periodically a consolidated NOA. This periodic NOA will announce the availability of all the COVID-19-related guidance documents that issued during the relevant period. The consolidated NOA will provide instructions to the public on submitting comments on COVID-19-related guidance documents, including the docket number(s) associated with each guidance document, information on how to view the dockets, and instructions for persons interested in obtaining a copy of a COVID-19-related guidance document. In addition, the guidance document will provide information to the public on submitting comments on the guidance document, including the docket number(s) associated with the guidance document and instructions for persons interested in obtaining a copy of a COVID-19-related guidance document.
- FDA intends to establish one docket for each Center or Office that may issue COVID-19-related guidance documents. All COVID-19-related guidance documents issued by that Center or Office will be available in the docket associated with the Center or Office that issues the guidance document. The docket numbers associated with each Center or Office that may issue COVID-19-related guidance documents are as follows:

Title of Docket (for each Center or Office)	Docket Number

Center for Drug Evaluation and Research (CDER) COVID-19	FDA-2020-D-1136
Center for Biologics Evaluation and Research (CBER) COVID-19	FDA-2020-D-1137
Center for Devices and Radiological Health (CDRH) COVID-19	FDA-2020-D-1138
Center for Food Safety and Applied Nutrition (CFSAN) COVID-19	FDA-2020-D-1139
Center for Veterinary Medicine (CVM) COVID-19	FDA-2020-D-1140
Center for Tobacco Products (CTP) COVID-19	FDA-2020-D-1141
Office of the Commissioner (OC) COVID-19	FDA-2020-D-1142
Office of Regulatory Affairs (ORA) COVID-19	FDA-2020-D-1143

Dated: March 20, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-06222 Filed: 3/20/2020 11:15 am; Publication Date: 3/25/2020]