and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary B. Jones, 

AGCF/OPRE Certifying Officer.

BILLING CODE 4184-83-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


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.

FOR FURTHER INFORMATION CONTACT:

Kimberly Thomas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6220, Silver Spring, MD 20993–0002, 301–796–2357; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993–0002, 240–402–7911; Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–6353; Phil Chao, Center for Food Safety and Applied Nutrition, Food and Drug Administration, CPK1 Rm. 1C001, College Park, MD 20740, 240–402–2112; Diane Heinz, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., MPN2 RME435, HVF–6, Rockville, MD 20855, 240–402–5692; Mary 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 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 may also be accessed from the FDA web page 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 related to the COVID–19 public health emergency. Each such docket will announce the availability of all the COVID–19-related guidance documents that issued during the relevant period.
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:

<table>
<thead>
<tr>
<th>Title of Docket (for each Center or Office)</th>
<th>Docket No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center for Drug Evaluation and Research (CDER) COVID–19</td>
<td>FDA–2020–D–1136</td>
</tr>
<tr>
<td>Center for Biologics Evaluation and Research (CBER) COVID–19</td>
<td>FDA–2020–D–1137</td>
</tr>
<tr>
<td>Center for Devices and Radiological Health (CDRH) COVID–19</td>
<td>FDA–2020–D–1138</td>
</tr>
<tr>
<td>Center for Veterinary Medicine (CVM) COVID–19</td>
<td>FDA–2020–D–1139</td>
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<tr>
<td>Center for Tobacco Products (CTP) COVID–19</td>
<td>FDA–2020–D–1140</td>
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<tr>
<td>Office of Regulatory Affairs (ORA) COVID–19</td>
<td>FDA–2020–D–1142</td>
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</tbody>
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Miguelina Perez,
Program Analyst, Office of Federal Advisory Committee Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of General Medical Sciences Special Emphasis Panel, April 3, 2020, 8:00 a.m. to April 3, 2020, 6:00 p.m., The Hyatt House, Potomac Conference Room, The Wharf, 725 Wharf Street SW, Washington, DC 20024 which was published in the Federal Register on December 19, 2019, 84 FR 69756.

The meeting notice is amended to change the meeting location, times, and format. The meeting will now be held on May 13, 2020, 9:00 a.m. to May 14, 2020, 11:30 a.m. as a Video-Assisted Meeting at National Cancer Institute (NCI) Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850. The meeting is closed to the public.

Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, April 14, 2020, 08:00 a.m. to April 14, 2020, 05:00 p.m., Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), Conference Room Auburn, 8120 Wisconsin Avenue, Bethesda, MD 20814 which was published in the Federal Register on March 09, 2020, 85 FR 13667.

The meeting notice is amended to change the Meeting Format from Regular Meeting on April 14, 2020 to a Teleconference Meeting on April 14, 2020. The meeting is closed to the public.

Miguelina Perez,
Program Analyst, Office of Federal Advisory Committee Policy.

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Allergy and Infectious Diseases Ad Hoc Panel for Scientific Review, April 14, 2020, 1:00 p.m. to April 14, 2020, 5:00 p.m., 4300 Military Road NW, Washington, DC 20015 which was published in the Federal Register on December 20, 2019, 84 FR 70202.

This meeting notice is amended to change the meeting location, times, and format. The meeting will now be held on May 13, 2020, 9:00 a.m. to May 14, 2020, 11:30 a.m. as a Video-Assisted Meeting at National Cancer Institute (NCI) Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850. The meeting is closed to the public.

Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Allergy and Infectious Diseases Ad Hoc Panel for Scientific Review, April 14, 2020, 1:00 p.m. to April 14, 2020, 5:00 p.m., 4300 Military Road NW, Washington, DC 20015 which was published in the Federal Register on December 20, 2019, 84 FR 70202.

This meeting notice is amended to change the meeting location, times, and format. The meeting will now be held on May 13, 2020, 9:00 a.m. to May 14, 2020, 11:30 a.m. as a Video-Assisted Meeting at National Cancer Institute (NCI) Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850. The meeting is closed to the public.

Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Advisory Council, March 30, 2020, 8:30 a.m. to 3:00 p.m. at National Institutes of Health, 6700B Rockledge Drive, Conference Room A&B, Bethesda, MD 20817 which was published in the Federal Register on January 30, 2020, 85 FR 54599, and change in format published in the Federal Register on March 17, 2020, 85 FR 15206.

The meeting will be held at National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, March 30, 2020, 1:00 p.m. to 3:00 p.m. This meeting will be held by videoconference only.


For additional information, please visit: https://public.csr.nih.gov/AboutCSR/AboutCSR/Organization/CSRAdvisoryCouncil.

The meeting is open to the public.

Ronald J. Livingston, Jr.,
Program Analyst, Office of Federal Advisory Committee Policy.

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