Louis, MO 63197–9000. Note: in no case should the payment for the fee be submitted to FDA with the application.

When paying by wire transfer, the invoice number needs to be included; without the invoice number, the payment may not be applied and the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a payment by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, FDA Deposit Account Number: 75060099, U.S. Department of the Treasury routing/transit number: 021030004, SWIFT Number: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the application arrives at FDA's CVM. FDA records the official application receipt date as the later of the following: the date the application was received by FDA's CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Treasury notifies FDA of receipt of an electronic or wire transfer payment. U.S. Bank and the U.S. Treasury are required to notify FDA within 1 working day, using the PIN described previously.

The tax identification number of FDA is 53–0196965.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log on to the ADUFA website at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/animal-drug-user-fee-cover-sheet* and, under Application Submission Information, click on ''Create ADUFA User Fee Cover Sheet.'' For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or supplement. Once you are satisfied that the data on the cover sheet are accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three—Send the payment for your application as described in section IX.A.

Step Four—Please submit your application and a copy of the completed Animal Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product, Establishment, and Sponsor Fees

By December 31, 2020, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2021 using this fee schedule. Payment will be due by January 31, 2021. FDA will issue invoices in November 2021 for any products, establishments, and sponsors subject to fees for FY 2021 that qualify for fees after the December 2020 billing.

Dated: July 29, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16839 Filed 7–30–20; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–D–1106, FDA–2020–D–1136, FDA–2020–D–1137, FDA–2020–D–1138, FDA–2020–D–1139, and FDA–2020–D–1140]

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 guidance documents 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 August 3, 2020. The guidance documents have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.

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.

• 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 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 document.

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; Erica Takai, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, HFZ–450, Silver Spring, MD 20993–0002, 301–796–6353; Phil Chao, Center for Food Safety and Applied Nutrition (CFSAN), CPK1 Rm 1C001, HFS–024, Food and Drug Administration, College Park, MD 20740, 240–402–2112; Diane Heinz, Center for Veterinary Medicine (CVM), Food and Drug Administration, MPN2 RME435 HFV–6, 7500 Standish Pl., Rockville, MD 20855, 240–402–5692.

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 (PHS Act), determined that a PHE 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]

[1] On April 21, 2020, the PHE Determination was extended, effective April 26, 2020; on July 23, 2020, it was extended again, effective July 25, 2020. These PHE Determinations are 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://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.*

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 guidance documents 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 implements COVID–19-related guidance documents. Therefore, FDA 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 (FD&C Act) (21 U.S.C. 371(h)(1)(C) and 21 CFR 10.115(g)(2) (§ 10.115(g)(2))). The guidances are available at FDA's web page titled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders'' (*https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders*) and through FDA's web page titled ''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 document, FDA intends to publish periodically a consolidated NOA announcing the availability of certain COVID–19-related guidance documents 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 guidance documents:

TABLE 1—GUIDANCE RELATED TO THE COVID–19 PUBLIC HEALTH EMERGENCY

Docket No.	Center	Title of guidance	Contact information to request single copies
FDA–2020–D–1106	CDER	Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19) (March 2020) (Updated June 1, 2020).	*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	Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (March 2020) (Updated June 1, 2020).	*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 Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19) (March 2020) (Updated June 1, 2020).	*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–1136	CDER	Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During the COVID–19 Public Health Emergency (June 8, 2020).	*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 ..... CBER, CDRH, CVM ...	Statistical Considerations for Clinical Trials During the COVID–19 Public Health Emergency Guidance for Industry (June 2020).	*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, CVM, CBER ...	Good Manufacturing Practice Considerations for Responding to COVID–19 Infection in Employees in Drug and Biological Products Manufacturing (June 2020).	*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–1137	CBER	Development and Licensure of Vaccines to Prevent COVID–19 (June 2020).	Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Phone 1–800–835–4709 or 240–402–8010, email *ocod@fda.hhs.gov.*
FDA–2020–D–1138	CDRH	Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (Revised) (March 20, 2020) (Updated June 5, 2020).	*CDRH-Guidance@fda.hhs.gov.* Please include the document number 20014 and complete title of the guidance in the request.
FDA–2020–D–1138	CDRH	Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID–19 Public Health Emergency (May 6, 2020) (Updated June 19, 2020).	*CDRH-Guidance@fda.hhs.gov.* Please include the document number 20032 and complete title of the guidance in the request.
FDA–2020–D–1138	CDRH, CBER	Effects of the COVID–19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices—Questions and Answers (June 2020).	*CDRH-Guidance@fda.hhs.gov.* Please include the document number 20040 and complete title of the guidance in the request.
FDA–2020–D–1139	CFSAN	Reporting a Temporary Closure or Significantly Reduced Production by a Human Food Establishment and Requesting FDA Assistance During the COVID–19 Public Health Emergency (May 27, 2020).	*INFOCenter-CFSAN@fda.hhs.gov.* Please include the docket number, FDA–2020–D–1139, and complete title of the guidance in the request.

Although these guidance documents 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. CDER Guidances

The guidances listed in the table below refer 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 guidance have been approved by OMB as listed in the following table:

TABLE 2—CDER GUIDANCES AND COLLECTIONS

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance referenced in COVID–19 guidance	OMB Control No(s).
Good Manufacturing Practice Considerations for Responding to COVID–19 Infections in Employees in Drug and Biological Products Manufacturing—June 2020.	21 CFR 211, 211.22, 211.28(d), 211.100. 21 CFR 212.20, 212.30, 212.50, 212.70, 212.71 21 CFR 600.10(c)(1)	(1) ICH Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients. (2) ICH Q5A Viral Safety Evaluation of biotechnology Products Derived From Cell Lines of Human or Animal Origin. (3) ICH Q9 Quality Risk Management ..... (4) Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products. (5) Enforcement Policy for Sterilizers, disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency. (6) Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID–19 Public Health Emergency. (7) GFI #271 Reporting and Mitigating Animal Drug Shortages during the COVID–19 Public Health Emergency.	0910–0130 0910–0139 0910–0667 0910–0675 0910–0759 0910–0032 0910–0669
Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples during the COVID–19 Public Health Emergency—Guidance for Industry.	21 CFR 203	.....	0910–0435
Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19)—UPDATE of guidance announced in March 2020.	27 CFR Part 20 and 21	(1) Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19). (2) Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19). (3) Adverse Event Reporting Requirements	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)—UPDATE of guidance announced in March 2020.	27 CFR Part 20 and 21	None	0910–0045 0910–0139 0910–0230 0910–0291 0910–0340 0910–0641 0910–0645 0910–0800
Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry—UPDATE of guidance announced in March 2020.	.....	(1) Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19). (2) Temporary Policy for Manufacture of Alcohol for Incorporation into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19).	0910–0045 0910–0139 0910–0230 0910–0291 0910–0340 0910–0641 0910–0645 0910–0800

The guidance, Statistical Considerations for Clinical Trials during the COVID–19 Public Health Emergency, contains no collection of information. Therefore, clearance by OMB under the PRA is not required.

B. CBER Guidances

The guidance listed in the table below refer to previously approved collection of information. This collection of information is subject to review by the OMB under the PRA. The collection of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

TABLE 3—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).
Development and Licensure of Vaccines to Prevent COVID–19.	21 CFR part 312		0910–0114
	21 CFR part 58		0910–0119
	21 CFR part 50		0910–0130
	21 CFR parts 210, 211, and 610.		0910–0139
	221 CFR part 600		0910–0308
	221 CFR part 601		0910–0338
		—Form FDA 3500A	0910–0291
		—Establishment and Operation of Clinical Trial Data Monitoring Committees.	0910–0581
		—Emergency Use Authorization of Medical Products and Related Authorities.	0910–0595

C. CDRH Guidances

The guidances listed in the table below refer to previously approved collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

TABLE 4—CDRH 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).
Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (Revised) (March 20, 2020) (Updated June 5, 2020).	807, subpart E		0910–0120
	800, 801, and 809		0910–0485
Effects of the COVID–19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices—Questions and Answers (June 22, 2020).		Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program: Guidance for Industry and Food and Drug Administration Staff.	0910–0756
		Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders.	0910–0595
	814, subparts A through E.		0910–0231
	807, subpart E		0910–0120
		De Novo Classification Process (Evaluation of Automatic Class III Designation): Guidance for Industry and Food and Drug Administration Staff.	0910–0844
	814, subpart H		0910–0332
	812		0910–0078

The guidance indicated in the table below refers to previously approved collections of information. These collections of information are subject to review by the OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the 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 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.*

TABLE 5—CDRH GUIDANCES AND COLLECTIONS

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
Notifying CDRH of Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID–19 Public Health Emergency (Revised) (May 6, 2020) (Updated June 19, 2020).	807, subparts A through D.	Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders.	0910–0625 0910–0595	Notifications to FDA about changes in the production of certain medical device products that will help the Agency prevent or mitigate shortages of such devices during the COVID–19 public health emergency. Updates to FDA every two weeks after initial notification on the shortage situation, including the expected timeline for recovery. Voluntary submission of other information that enables FDA to work more effectively with manufacturers and other entities to prevent or limit any negative impact on patients or healthcare providers during the COVID–19 public health emergency.

D. CFSAN Guidances

The guidance indicated in the table below refers to previously approved collections of information. These collections of information are subject to review by the OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the 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 PHE waiver from the PRA by 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.*

TABLE 6—CFSAN GUIDANCES AND COLLECTIONS

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
Reporting a Temporary Closure or Significantly Reduced Production by a Human Food Establishment and Requesting FDA Assistance During the COVID–19 Public Health Emergency.	21 CFR part 1, subpart H.	.....	0910–0502	Establishments have the option to report to FDA temporary closures or significant reductions of production and to request assistance from FDA.

IV. Electronic Access

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

- The 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;*
- the 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: July 28, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16852 Filed 7–31–20; 8:45 am]

BILLING CODE 4164–01–P