4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Guidance Documents Related to Coronavirus Disease 2019 (COVID-19); 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 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, document. 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 **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. 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 § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Submit written requests for single copies of any of these guidances to the addresses noted in table 1. Where applicable, 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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, 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, 5001 Campus Dr., College Park, MD 20740, 240-402-2112; 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; Diane Heinz, Center for Veterinary Medicine, Food and Drug Administration, 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 (HHS), pursuant to the authority under section 319 of the Public Health Service Act (PHS Act) (42 U.S.C. 247d), 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]

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 § 10.115(g)(2)). The guidances are available on FDA's web page "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 "Search for FDA Guidance Documents" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents).

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[1] On April 21, 2020, the PHE Determination was extended, effective April 26, 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/.

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

Lastly, the March 25, 2020, notice indicated that, in general, guidance documents would be placed in dockets established for COVID-19-related guidance documents issued by each Center. As noted in table 1, certain COVID-19-related guidance documents issued by the Center for Drug Evaluation and Research (CDER) prior to March 24, 2020, were placed in Docket No. FDA-2020-D-1106. FDA anticipates that, in general, CDER will use Docket No. FDA-2020-D-1136 for additional COVID-19-related guidance documents issued pursuant to the process described in the March 25, 2020, notice.

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

Docket No.	Center/Office	Title of Guidance	Contact Information to Request Single Copies
FDA-2020-D-1137	Center for Biologics Evaluation and Research (CBER)	Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency (April 2020)	Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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-1138	Center for Devices and Radiological Health (CDRH)	Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019 (COVID-19) Public Health Emergency (March 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	Enforcement Policy for Ventilators and Accessories and	CDRH-Guidance@fda.hhs.gov Please include the document

		Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (March 2020)	number 20015 and complete title of the guidance in the request.
FDA-2020-D-1138	CDRH	Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (March 2020)	CDRH-Guidance@fda.hhs.gov Please include the document number 20019 and complete title of the guidance in the request.
FDA-2020-D-1138	CDRH	Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency (March 2020)	CDRH-Guidance@fda.hhs.gov Please include the document number 20020 and complete title of the guidance in the request.
FDA-2020-D-1138	CDRH	Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Issued March 25, 2020) (Revised April 2, 2020)	CDRH-Guidance@fda.hhs.gov Please include the document number 20018 and complete title of the guidance in the request.
FDA-2020-D-1139	Center for Food Safety and Applied Nutrition (CFSAN)	Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID-19 Public Health Emergency (March 2020)	Office of Nutrition and Food Labeling, Food Labeling and Standards Staff, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740
FDA-2020-D-1139	CFSAN	Temporary Policy Regarding Nutrition Labeling of Standard Menu Items in Chain Restaurants and Similar Retail Food Establishments During the COVID-19 Public Health Emergency (April 2020)	Office of Nutrition and Food Labeling, Food Labeling and Standards Staff, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740
FDA-2020-D-1139	CFSAN	Temporary Policy Regarding Packaging and Labeling of Shell Eggs Sold by Retail Food Establishments During the COVID-19 Public Health Emergency (April 2020)	Office of Nutrition and Food Labeling, Food Labeling and Standards Staff, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740
FDA-2020-D-1106	CDER	FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency (March 18, 2020) (Updated March 27, 2020, April 2, 2020, and April 16, 2020)	Clinicaltrialconduct-COVID19@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) (March 19, 2020) (Updated March 27,	druginfo@fda.hhs.gov Please include the docket number FDA-2020-D-1106 and complete title of the guidance in the request.

		2020, and April 15, 2020)	
FDA-2020-D-1106	CDER	Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency (March 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) Guidance for Industry (March 24, 2020) (Updated March 27, 2020, and April 15, 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 April 15, 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-1140	Center for Veterinary Medicine (CVM)	CVM GFI #269 - Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID-19 Outbreak (March 2020)	AskCVM@fda.hhs.gov Please include the docket number FDA-2020-D-1140 and complete title of the guidance in the request.
FDA-2020-D-1140	CVM	CVM GFI #270 - Guidance on the Conduct and Review of Studies to Support New Animal Drug Development during the COVID-19 Public Health Emergency (April 2020)	AskCVM@fda.hhs.gov Please include the docket number FDA-2020-D-1140 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)).

III. Significance of Guidances

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.

IV. Paperwork Reduction Act of 1995

A. Center for Biologics Evaluation and Research

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 (44 U.S.C. 3501-3521) (PRA). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

COVID-19 Guidance Title	21 CFR Cite Referenced in COVID-19 Guidance	Another Guidance Title Referenced in COVID-19 Guidance	OMB Control No(s).
Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency	601.12 640.120 part 630	N/A	0910-0338 0910-0338 0910-0116

B. Center for Devices and Radiological Health

These guidances 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:

COVID-19 Guidance Title	21 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	807, subpart E		0910-0120
	800, 801, and 809		0910-0485
Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	800, 801, and 809		0910-0485
	803		0910-0437
	807, subpart E		0910-0120
	812		0910-0078
	820		0910-0073
		Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders	0910-0595
Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers	800, 801, and 809		0910-0485
	807, subpart E		0910-0120

During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	807, subparts A through D		0910-0625
	814, subparts A through E		0910-0231
	820		0910-0073
	830 and 801.20		0910-0720
Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency	800, 801, and 809		0910-0485
	806		0910-0359
	807, subparts A through D		0910-0625
	807, subpart E		0910-0120
	820		0910-0073
	830 and 801.20		0910-0720
Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)	800, 801, and 809		0910-0485
	803		0910-0437
	806		0910-0359
	807, subpart E		0910-0120
	807, subparts A through D		0910-0625
	820		0910-0073
	830 and 801.20		0910-0720
		Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders	0910-0595

C. Center for Food Safety and Applied Nutrition

These guidances 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 guidances have been approved by OMB as listed in the following table:

COVID-19 Guidance Title	21 CFR Cite Referenced in COVID-19 Guidance	Another Guidance Title Referenced in COVID-19 Guidance	OMB Control No(s).
Temporary Policy Regarding Nutrition Labeling of Standard Menu Items in Chain Restaurants and Similar Retail Food Establishments During the COVID-19 Public Health Emergency	101.11		0910-0782
Temporary Policy Regarding Packaging and Labeling of Shell Eggs Sold by Retail Food	part 101	Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the	0910-0381

Establishments During the COVID-19 Public Health Emergency		COVID19 Public Health Emergency; 0910-0381, 0910-0792	

This guidance refers 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 table below. 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.

COVID-19 Guidance Title	21 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
Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID-19 Public Health Emergency	part 101; section 403(w) of the FD&C Act (21 U.S.C. 343(w))		0910-0381, 0910-0792	If a food product does not have the required labeling information, a restaurant may create a label to include this information (new respondent).

D. Center for Drug Evaluation and Research

This guidance refers 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 guidances have been approved by OMB as listed in the following table:

COVID-19 Guidance Title	21 CFR Cite Referenced in COVID-19 Guidance	Another Guidance Referenced in COVID-19 Guidance	OMB Control No(s).
FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency (Updated)	50.27(a) 312.30 312.60	Use of Electronic Informed Consent in Clinical Investigations	0910-0001 0910-0014 0910-0755

	312.62 812.35(a) 812.140			

These guidances 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 table below. These guidances also contain 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.

COVID-19 Guidance Title	21 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
Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)		Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Providing Regulatory Submissions in Electronic Format - Drug Establishment Registration and Drug Listing Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application	0910-0045 0910-0139 0910-0230 0910-0291 0910-0340 0910-0641 0910-0645 0910-0800	For proposed use of an alternative grade of ethanol, firms are requested to submit to FDA information on the ethanol concentration and levels of impurities listed in the USP monograph and other potentially harmful impurities in the manufacturing environment.
Policy for Temporary		Current Good Manufacturing Practices	0910-0139 0910-0230	For proposed use of an alternative grade of ethanol,

Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (Updated)		for Finished Pharmaceuticals and Medical Gases Postmarketing Adverse Drug Experience Reporting MedWatch: Adverse Event and Product Experience Reporting System (Paper-Based) Format and Content Requirements for Over-the-Counter Drug Product Labeling FDA Adverse Event and Product Experience Reports; Electronic Submissions Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act Temporary Policy for Preparation 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)	0910-0291 0910-0340 0910-0645	firms are requested to submit to FDA information on the ethanol concentration and levels of impurities listed in the USP monograph and other potentially harmful impurities in the manufacturing environment.
Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)		Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Providing Regulatory Submissions in Electronic Format - Drug Establishment Registration and Drug Listing	0910-0045 0910-0139 0910-0230 0910-0291 0910-0340 0910-0641 0910-0645	For proposed use of an alternative grade of ethanol, firms are requested to submit to FDA information on the ethanol concentration and levels of impurities listed in the USP monograph and other potentially harmful impurities in the manufacturing environment.

The final guidance entitled "Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency" contains no collection of information. Therefore, clearance by OMB under the PRA is not required.

E. Center for Veterinary Medicine

This guidance refers 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:

COVID-19 Guidance Title	21 CFR cite Referenced in COVID-19 Guidance	Another Guidance Title Referenced in COVID-19 Guidance	OMB Control No(s).
GFI #270 - Guidance on the Conduct and Review of Studies to Support New Animal Drug Development during the COVID-19 Public Health Emergency		FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency	0910-0032 0910-0669

The final guidance entitled "GFI #269 - Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID-19 Outbreak" contains no collection of information. Therefore, clearance by OMB under the PRA is not required.

V. Electronic Access

Persons with access to the internet may obtain COVID-19-related guidances at the FDA web page "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 "Search for FDA Guidance Documents," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents; or https://www.regulations.gov.

Dated: May 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-10146 Filed: 5/11/2020 8:45 am; Publication Date: 5/12/2020]