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-1138, FDA-2020-D-1139, 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 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 [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, 240-402-7500.

- 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, 240-402-7500.

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 addresses 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 documents.

FOR FURTHER INFORMATION CONTACT: 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 (42 U.S.C. 247d) (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]

In the *Federal Register* of March 25, 2020 (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 entitled "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 entitled "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

[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/.

periodically a consolidated NOA announcing the availability of certain COVID-19-related guidance documents 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.--Guidances Related to the COVID-19 Public Health Emergency

Docket No.	Center	Title of Guidance	Contact Information to Request Single Copies
FDA-2020-D-1138	CDRH	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 (May 6, 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	Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (May 21, 2020)	CDRH-Guidance@fda.hhs.gov Please include the document number 20028 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 (April 2020) (Updated May 26, 2020)	CDRH-Guidance@fda.hhs.gov Please include the document number 20018 and complete title of the guidance in the request.
FDA-2020-D-1138	CDRH	Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (May 26, 2020)	CDRH-Guidance@fda.hhs.gov Please include the document number 20033 and complete title of the guidance in the request.
FDA-2020-D-1136	CDER	Exemption and Exclusion of Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency (April 30, 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	COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requirements for COVID-19 Related Drugs and Biological Products (May 11, 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	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 (April 10, 2020) (Updated May 14, 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	Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency (April 2020)	druginfo@fda.hhs.gov Please include the docket number FDA-2020-D-1136 and complete title of the guidance in the request.

		(Updated May 21, 2020)	
FDA-2020-D-1136	CDER	Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency (April 2020) (Updated May 21, 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	Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications--Questions and Answers (May 26, 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-1106	CDER	FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency (March 2020) (Updated May 14 and June 3, 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-1139	CFSAN	Returning Refrigerated Transport Vehicles and Refrigerated Storage Units to Food Uses After Using Them to Preserve Human Remains During the COVID-19 Pandemic (May 12, 2020)	Retail Food Protection Staff, Office of Food Safety, 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 Certain Food Labeling Requirements During the COVID-19 Public Health Emergency: Minor Formulation Changes and Vending Machines (May 22, 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-1140	CVM	GFI# 271 Reporting and Mitigating Animal Drug Shortages during the COVID-19 Public Health Emergency (May 7, 2020)	AskCVM@fda.hhs.gov. Please include the docket number FDA-2020-N-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)).

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. 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 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.--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).
Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.	21 CFR part 814, subparts A through E		0910-0231
	21 CFR part 814, subpart H		0910-0332
	21 CFR part 820		0910-0073
	21 CFR parts 800, 801, and 809		0910-0485
Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Face Masks and Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.	21 CFR part 803		0910-0437
		Emergency Use Authorization of Medical Products and Related Authorities.	0910-0595
Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency.	21 CFR parts 800, 801, and 809		0910-0485
	21 CFR part 803		0910-0437
	21 CFR part 806		0910-0359
	21 CFR part 807, subpart E		0910-0120
	21 CFR part 807, subparts A through D		0910-0625
	21 CFR part 820		0910-0073
	21 CFR part 830 and 801.20		0910-0720
		Emergency Use Authorization of Medical Products and Related Authorities.	0910-0595

The guidance indicated in the table below 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. 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 3.-- CDRH Guidance 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.	21 CFR part 807, subparts A through D		0910-0625	
		Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders.	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 PHE.
				Updates to FDA every 2 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 PHE.

B. 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 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:

Table 4.CDER 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).
Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications.	§ 10.115(g)(2)	Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products. Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products. Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products.	0910-0001 0910-0014 0910-0429 0910-0693 0910-0718 0910-0719 0910-0727
Exemption and Exclusion of Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency.		Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification. Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs. Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act.	0910-0777 0910-0800 0910-0806 0910-0827 0910-0859
General Considerations for Pre-IND Meeting Requirements for COVID-19 Related Drugs and Biological Products.	21 CFR part 312	COVID-19: Developing Drugs and Biological Products for Treatment or Prevention. Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products. Emergency Use Authorization of Medical Products and Related Authorities. Preclinical Assessment of Investigational Cellular and Gene Therapy Products. Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees. Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments. Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products.	0910-0001 0910-0014 0910-0338 0910-0429 0910-0595 0910-0719 0910-0814

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 guidances have been

approved by OMB as listed in the below table. These guidances also contain new collections of information not approved under a current collection. These new collections of information have 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 5.-- 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).	New Collection Covered by PHE PRA Waiver
Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency.	21 CFR 314.81 21 CFR 600.82	Current Good Manufacturing Practice--Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.	0910-0777 0910-0338 0910-0001 0910-0139	To provide suitability and proof of sterility for the container closure systems used.
Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency.		Compounded Drug Products That are Essentially Copies of a Commercially Available Drug Product under Section 503A of the Federal Food, Drug, and Cosmetic Act. Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency. Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act. 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.	0910-0001 0910-0139 0910-0338	For reporting of adverse events by pharmacy compounders to the MedWatch system and maintaining records of drugs suppliers and patients who receive the compounded products.
Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy	21 CFR parts 210 and 211	Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised). Enforcement Policy for Gowns,	0910-0139	Recordkeeping of compounding performed without standard PPE; recordkeeping of any change of

Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency.		Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency. Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.		sterilization/aseptic processing methods; documentation of mitigation strategies for sterile compounding without standard PPE.
Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency.	21 CFR part 11 21 CFR part 50 21 CFR part 56 21 CFR part 312 21 CFR part 314 21 CFR part 601 21 CFR part 812	Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products. Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products. Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans. Draft Guidance for Industry on Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products. Enhancing the Diversity of Clinical Trial Populations--Eligibility Criteria, Enrollment Practices, and Trial Design. Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials. Part 11, Electronic Records; Electronic Signatures Scope and Application. Use of Electronic Records and Electronic Signatures in Clinical Investigations under 21 CFR Part 11--Questions and Answers. Safety Reporting Requirements for INDs and BA/BE Studies. Adverse Event Reporting to IRBs--Improving Human Subject Protection. Use of Electronic Informed Consent In Clinical Investigations. E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1). Providing Regulatory Submissions in Electronic	0910-0001 0910-0014 0910-0130 0910-0303 0910-0338 0910-0119 0910-0581 0910-0733 0910-0078	Submission by investigators of informed consent forms to third parties.

		Format--Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications. Best Practices for Communication Between IND Sponsors and FDA During Drug Development. Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.		

C. CFSAN Guidance

The guidance indicated in the table below 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. 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 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 Guidance 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
Temporary Policy Regarding Certain Mandatory Food Labeling Requirements During the COVID-19 Public Health Emergency: Minor Formulation Changes and Vending Machines.	21 CFR part 101; section 403(w) of the FD&C Act		0910-0381 0910-0782 0910-0792	Recommend that manufacturers post ingredient omissions or substitutions not reflected on the product label.

The guidance entitled "Returning Refrigerated Transport Vehicles and Refrigerated Storage Units to Food Uses After Using Them to Preserve Human Remains During the COVID-

19 Pandemic" contains no collection of information. Therefore, clearance by OMB under the PRA is not required.

D. CVM Guidance

This guidance indicated in the table below 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 indicated 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 7.--CVM Guidance and Collection

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
GFI# 271, Reporting and Mitigating Animal Drug Shortages during the COVID-19 Public Health Emergency.	21 CFR 514.1(a))		0910-0032 0910-0669	Reporting and mitigating animal drug shortages.

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: June 22, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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