By direction of the Commission.

April J. Tabor,

Acting Secretary.

[FR Doc. 2020–10081 Filed 5–11–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–8003]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by July 13, 2020.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-8003 1915(c) Home and Community Based Services (HCBS) Waiver

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* 1915(c) Home and Community Based Services (HCBS) Waiver; *Use:* We will use the web-based application to review and adjudicate individual waiver actions. The web-based application will also be used by states to submit and revise their waiver requests. *Form Number:* CMS–8003 (OMB control number 0938–0449); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 47; *Total Annual Responses:* 71; *Total Annual Hours:* 6,005. (For policy questions regarding this collection contact Kathy Poisal at 410–786–5940.)

Dated: *May 7, 2020.*

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–10095 Filed 5–11–20; 8:45 am]

BILLING CODE 4120–01–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 May 12, 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 § 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-*

[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/.*

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*).

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 Other Respiratory Devices During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (March 2020).	*CDRH-Guidance@fda.hhs.gov.* Please include the document 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, 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.

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

Docket No.	Center/office	Title of guidance	Contact information to request single copies
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 800, 801, and 809		0910–0120 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 809 803 807, subpart E 812 820		0910–0485 0910–0437 0910–0120 0910–0078 0910–0073

COVID–19 guidance title	21 CFR Cite referenced in COVID–19 Guidance	Another guidance title referenced in COVID–19 guidance	OMB Control No(s).
		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 During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	800, 801, and 809 807, subpart E 807, subparts A through D 814, subparts A through E 820 830 and 801.20		0910–0485 0910–0120 0910–0625 0910–0231 0910–0073 0910–0720
Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID–19) Public Health Emergency.	800, 801, and 809 806 807, subparts A through D 807, subpart E 820 830 and 801.20		0910–0485 0910–0359 0910–0625 0910–0120 0910–0073 0910–0720
Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID–19) Public Health Emergency (Revised).	800, 801, and 809 803 806 807, subpart E 807, subparts A through D 820 830 and 801.20		0910–0485 0910–0437 0910–0359 0910–0120 0910–0625 0910–0073 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 Establishments During the COVID–19 Public Health Emergency.	part 101	Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID19 Public Health Emergency; 0910–0381, 0910–0792.	0910–0381

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) 312.30 312.60 312.62 812.35(a) 812.140	Use of Electronic Informed Consent in Clinical Investigations.	0910–0001 0910–0014 0910–0755

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.

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
Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (Updated).	.....	Current Good Manufacturing Practices 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).	0910–0139 0910–0230 0910–0291 0910–0340 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.
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 5–11–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1081]

Hospira Inc., et al.; Withdrawal of Approval of Seven Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of seven abbreviated new drug applications (ANDAs) from multiple applicants. The