validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.9(c)(1).

++ TJC's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ TJC's capacity to provide CMS with electronic data and reports necessary for the effective validation and assessment of the organization's survey process.

++ The adequacy of TJC's staff and other resources, and its financial viability.

++ TJC's capacity to adequately fund required surveys.

++ TJC's policies with respect to whether surveys are announced or unannounced, to ensure that surveys are unannounced.

++ TJC's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ TJC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

## IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

## V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including our evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: May 7, 2020.

**Evell J. Barco Holland,**

*Federal Register Liaison, Department of Health and Human Services.*

[FR Doc. 2020–11234 Filed 5–22–20; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2020–D–1136, FDA–2020–D–1137, FDA–2020–D–1138, FDA–2020–D–1139]**

### 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 guidances 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 26, 2020. The guidances 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(s) 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 any 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 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. 7268, Silver Spring, MD 20993–0002, 240–402–7911; Erica Takai, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–6353; 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; 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.

**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 guidances 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 guidances. Therefore, FDA will issue COVID–19-related guidances 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, FDA intends to publish periodically a consolidated NOA announcing the availability of certain COVID–19-related guidances 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 Guidances

Pursuant to the process described in the March 25, 2020, notice, FDA is announcing the availability of the following COVID–19-related guidances:

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 ..... | CBER | Investigatory COVID–19 Convalescent Plasma (April 2020) (Updated May 1, 2020). | Office of Communication, Outreach and Development, 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 ..... | CDRH | Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (April 4, 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 Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (April 5, 2020). | *CDRH-Guidance@fda.hhs.gov* Please include the document number 20014 and complete title of the guidance in the request. |

[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/.*

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–1138 ..... | CDRH | Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (April 6, 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 Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (April 6, 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 Digital Health Devices for Treating Psychological Disorders During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (April 14, 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 Telethermographic Systems During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (April 16, 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 Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (April 23, 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 Imaging Systems During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (April 23, 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 Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (April 24, 2020). | *CDRH-Guidance@fda.hhs.gov* Please include the document number 20014 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). | *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 | Policy for the Temporary Use of Portable Cryogenic Containers Not in Compliance With 21 CFR 211.94(e)(1) For Oxygen and Nitrogen During the COVID–19 Public Health Emergency (April 2020) (Updated April 20, 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 16, 2020) (Updated May 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 | 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 Guidance for Industry (April 20, 2020) (Updated May 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 | Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID–19 Public Health Emergency (April 22, 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–1139 ..... | CFSAN | Temporary Policy on Regulatory Enforcement of 21 CFR Part 118 (the Egg Safety Rule) During the COVID–19 Public Health Emergency (April 6, 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. |

Although these guidances 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. CBER*

The guidance indicated below 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:

TABLE 2—CBER GUIDANCE

| COVID–19 guidance title | CFR cite referenced in COVID–19 guidance | Another guidance title referenced in COVID–19 guidance | OMB control No(s). |
|---|---|---|---|
| Investigatory COVID–19 Convalescent Plasma. | 21 CFR part 312 | N/A | 0910–0014 |
| | ≤21 CFR 606.121 | | 0910–0116 |
| | 21 CFR part 630 | | 0910–0116 |
| | Form FDA 3926 | | 0910–0814 |

*B. CDRH*

The guidances listed 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:

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Table 3.--CDRH Guidances

| 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 Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency | 21 CFR part 807, subpart E<br>21 CFR part 806<br>21 CFR part 807, subparts A through D<br>21 CFR parts 830 & 801.20<br>21 CFR parts 800, 801, 809<br>21 CFR part 820 | | 0910-0120<br>0910-0359<br>0910-0625<br>0910-0720<br>0910-0485<br>0910-0073 |
| Enforcement Policy for Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency | 21 CFR part 807, subpart E<br>21 CFR part 807, subparts A through D<br>21 CFR part 820<br>21 CFR part 806<br>21 CFR parts 830 and 801.20<br>21 CFR parts 800, 801, and 809<br>21 CFR part 803 | Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders | 0910-0595<br>0910-0120<br>0910-0625<br>0910-0073<br>0910-0359<br>0910-0720<br>0910-0485<br>0910-0437 |
| Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency | 21 CFR part 807, subpart E<br>21 CFR part 807, subparts A through D<br>21 CFR part 822<br>21 CFR part 820<br>21 CFR part 806<br>21 CFR parts 830 and 801.20<br>21 CFR parts 800, 801, and 809 | | 0910-0120<br>0910-0625<br>0910-0449<br>0910-0073<br>0910-0359<br>0910-0720<br>0910-0485 |
| Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency | 21 CFR part 807, subpart E<br>21 CFR part 814, subparts A through E<br>21 CFR parts 800, 801, and 809<br>21 CFR part 820<br>21 CFR part 803 | Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders | 0910-0595<br>0910-0120<br>0910-0231<br>0910-0485<br>0910-0073<br>0910-0437 |
| Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency | 21 CFR part 807, subpart E<br>21 CFR part 806<br>21 CFR part 807, subparts A through D<br>21 CFR parts 830 and 801.20<br>21 CFR parts 800, 801, and 809 | | 0910-0120<br>0910-0359<br>0910-0625<br>0910-0720<br>0910-0485 |

| | | | |
|---|---|---|---|
| Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency | 21 CFR parts 800, 801, and 809<br>21 CFR part 806<br>21 CFR part 807, subparts A through D<br>21 CFR part 807, subpart E<br>21 CFR part 820<br>21 CFR part 822<br>21 CFR parts 830 and 801.20 | | 0910-0485<br>0910-0359<br>0910-0625<br>0910-0120<br>0910-0073<br>0910-0449<br>0910-0720 |
| Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency | 21 CFR part 807, subpart E<br>21 CFR parts 800, 801, and 809<br>21 CFR part 820 | | 0910-0120<br>0910-0485<br>0910-0073 |
| Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency | 21 CFR parts 800, 801, and 809<br>21 CFR part 807, subpart E<br>21 CFR part 814, subparts A through E<br>21 CFR part 820<br>21 CFR parts 1000-1050 | | 0910-0485<br>0910-0120<br>0910-0231<br>0910-0073<br>0910-0025 |
| Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency | 21 CFR part 807, subpart E<br>21 CFR part 812<br>21 CFR part 820<br>21 CFR parts 830 and 801.20<br>21 CFR parts 800, 801, and 809<br>21 CFR part 814, subpart H<br>21 CFR part 820<br>21 CFR parts 800, 801, and 809 | Administrative Procedures for CLIA Categorization: Guidance for Industry and Food and Drug Administration Staff | 0910-0667<br>0910-0120<br>0910-0078<br>0910-0073<br>0910-0720<br>0910-0485<br>0910-0332<br>0910-0073<br>0910-0485 |

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*C. CDER*

The guidances listed 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—GUIDANCES AND REGULATIONS

| COVID–19 guidance title | CFR or FD&C Act cite referenced in COVID–19 guidance | Another guidance title referenced in COVID–19 guidance | OMB control No(s). |
|---|---|---|---|
| Policy for Temporary Use of Portable Cryogenic Containers Not in Compliance With 21 CFR 211.94 for Oxygen and Nitrogen During COVID–19 Public Health Emergency. | 21 CFR parts 201, 210, 211.84, 211.94, and 211.100. | Current Good Manufacturing Practice for Medical Gases Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements. | 0910–0139 |
| 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, Section 503B(b)(1)(A)(i) of the FD&C Act (21 U.S.C. 353b(b)(1)(A)(i). | Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act. | 0910–0777<br>0910–0338<br>0910–0001<br>0910–0139 |

TABLE 4—GUIDANCES AND REGULATIONS—Continued

| COVID–19 guidance title | CFR or FD&C Act cite referenced in COVID–19 guidance | Another guidance title referenced in COVID–19 guidance | OMB control No(s). |
|---|---|---|---|
| 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.<br>Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID–19 Public Health Emergency.<br>Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act.<br>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<br>0910–0139<br>0910–0338 |
| Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID–19 Public Health Emergency. | ..... | Repackaging of Certain Human Drugs by Pharmacies and Outsourcing Facilities.<br>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.<br>Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID–19 Public Health Emergency. | 0910–0139<br>0910–0572<br>0910–0777<br>0910–0800 |

The guidance indicated 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 below 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 5—NEW PRA INFORMATION COLLECTION

| COVID–19 guidance title | CFR cite referenced in COVID–19 guidance | Another guidance referenced in COVID–19 guidance | OMB control No. | New collection covered by PHE PRA waiver |
|---|---|---|---|---|
| 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. | 21 CFR parts 210 and 211. | Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID–19) Public Health Emergency (Revised).<br>Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID–19) Public Health Emergency.<br>Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act. | 0910–0139 | Recordkeeping of compounding without standard PPE; recordkeeping of any change of sterilization/aseptic processing methods; documentation of mitigation strategies for sterile compounding without standard PPE. |

*D. CFSAN*

The guidance indicated 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 following table:

TABLE 6—CFSAN GUIDANCE

| COVID–19 guidance title | CFR cite referenced in COVID–19 guidance | Another guidance title referenced in COVID–19 guidance | OMB control No. |
|---|---|---|---|
| Temporary Policy Regarding Enforcement of 21 CFR Part 118 (the Egg Safety Rule) During the COVID–19 Public Health Emergency. | 21 CFR part 118 ..... | ..... | 0910–0660 |

**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: May 19, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–11238 Filed 5–22–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS–0937–0198]**

## Agency Information Collection Request; 30-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before June 25, 2020.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0937–0198–30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Title of the Collection: Public Health Service Polices on Research Misconduct (42 CFR part 93)—OMB No. 0937–0198—Extension—Office of Research Integrity.**

*Abstract:* The Office of Research Integrity is requesting an extension on a currently approved collection. The purpose of the Institutional Assurance and Annual Report on Possible Research Misconduct form PHS–6349 is to provide data on the amount of research misconduct activity occurring in institutions conducting PHS-supported research. The purpose of the Assurance of Compliance by Sub-Award Recipients form PHS–6315 is to establish an assurance of compliance for a sub-awardee institution. Forms PHS 6349 and PHS–6315 are also used to provide an annual assurance that the institution has established and will follow administrative policies and procedures for responding to allegations of research misconduct that comply with the Public Health Service (PHS) Policies on Research Misconduct (42 CFR Part 93). Research misconduct is defined as receipt of an allegation of research misconduct and/or the conduct of an inquiry and/or investigation into such allegations. These data enable the ORI to monitor institutional compliance with the PHS regulation.

*Need and Proposed Use:* The information is needed to fulfill section 493 of the Public Health Service Act (42 U.S.C. 289b), which requires assurances from institutions that apply for financial assistance under the Public Health Service Act for any project or program that involves the conduct of biomedical or behavioral research. In addition, the information is also required to fulfill the assurance and annual reporting requirements of 42 CFR Part 93. ORI uses the information to monitor institutional compliance with the regulation. Lastly, the information may be used to respond to congressional requests for information to prevent misuse of Federal funds and to protect the public interest.

ESTIMATED ANNUALIZED BURDEN HOUR TABLE

| Forms (if necessary) | Type of respondent | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|---|
| PHS–6349 | Awardee Institutions | 5748 | 1 | 12/60 | 1150 |
| PHS–6315 | Sub-Awardee Institutions | 110 | 1 | 5/60 | 9 |
| Total | | | | | 1159 |