**Table 1.--Guidance Documents that Will No Longer Be in Effect**

**Upon Expiration of the COVID-19 PHE Declaration**

| Docket No. | Lead Center | Title of Guidance |
| --- | --- | --- |
| FDA-2020-D-1137 | **CBER** | Manufacturing Considerations for Licensed and Investigational Cellular and Gene Therapy Products During COVID-19 Public Health Emergency |
| FDA-2020-D-1136 | **CDER** | COVID-19 Public Health Emergency Policy on COVID-19-Related Sanitation Tunnels |
| FDA-2021-D-1311 | **CDER** | Nonclinical Considerations for Mitigating Nonhuman Primate Supply Constraints Arising from the COVID-19 Pandemic\* |
| FDA-2020-D-1136 | **CDER** | Development of Abbreviated New Drug Applications During the COVID-19 Pandemic--Questions and Answers |
| FDA-2020-D-1136 | **CDER** | Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID-19 Public Health Emergency |
| FDA-2020-D-1136 | **CDER** | Review Timelines for Applicant Responses to Complete Response Letters When a Facility Assessment Is Needed During the COVID-19 Public Health Emergency Guidance for Industry |
| FDA-2020-D-1136 | **CDER** | Resuming Normal Drug and Biologics Manufacturing Operations During the COVID-19 Public Health Emergency\* |
| FDA-2020-D-1136 | **CDER** | Good Manufacturing Practice Considerations for Responding to COVID-19 Infection in Employees in Drug and Biological Products Manufacturing\* |
| FDA-2020-D-1136 | **CDER** | Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency |
| FDA-2020-D-1136 | **CDER** | Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications--Questions and Answers |
| 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 |
| 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 |
| 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 |
| FDA-2020-D-1136 | **CDER** | Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During the COVID-19 Public Health Emergency\* |
| FDA-2020-D-1136 | **CDER** | COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products |
| FDA-2020-D-1136 | **CDER** | Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency4 |
| FDA-2020-D-1138 | CDRH | Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency (Revised) |
| FDA-2020-D-1138 | CDRH | Enforcement Policy for the Quality Standards of the Mammography Quality Standards Act During the COVID-19 Public Health Emergency\* |
| FDA-2020-D-1139 | CFSAN | Temporary Policy Regarding Enforcement of 21 CFR Part 118 (the Egg Safety Rule) During the COVID-19 Public Health Emergency |
| 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 |
| FDA-2020-D-1139 | CFSAN | Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID-19 Public Health Emergency |
| FDA-2020-D-1139 | CFSAN | Reporting a Temporary Closure or Significantly Reduced Production by a Human Food Establishment and Requesting FDA Assistance During the COVID-19 Public Health Emergency |

**Table 2.--Guidance Documents FDA is Revising to Continue in Effect**

**for 180 Days After the COVID-19 PHE Declaration Expires**

| Docket No. | Lead Center | Title of Guidance |
| --- | --- | --- |
| 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 Guidance for Industry |
| FDA-2020-D-1136 | **CDER** | Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers |
| FDA-2020-D-1106 | **CDER** | Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency Guidance for Industry and Health Care Professionals |
| FDA-2020-D 1138 | CDRH | Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency\* |
| FDA-2020-D-1138 | CDRH | Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency\* |
| 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\* |
| FDA-2020-D-1138 | CDRH | Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency\* |
| FDA-2020-D-1138 | CDRH | Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency\* |
| 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\* |
| FDA-2020-D-1138 | CDRH | Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency\* |
| FDA-2020-D-1138 | CDRH | Enforcement Policy for Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency\* |
| FDA-2020-D-1138 | CDRH | Enforcement Policy for Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency\*5 |
| FDA-2020-D-1138 | CDRH | Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency\* |
| FDA-2020-D-1138 | CDRH | Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency\* |
| 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\* |
| FDA-2020-D-1138 | CDRH | Enforcement Policy for Modifications to FDA Cleared Molecular Influenza and RSV Tests During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency\* |
| FDA-2020-D-1138 | CDRH | Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised)\* |
| FDA-2020-D-1138 | CDRH | Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised)\* |
| 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 |
| 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 |
| FDA-2020-D-1386 | CFSAN | Temporary Policy During the COVID-19 Public Health Emergency Regarding the Qualified Exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption |
| 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 |

**Table 3.--Guidance Documents FDA is Revising to Continue in Effect**

**for 180 Days After the PHE Declaration Expires,**

**During Which Time FDA Plans to Further Revise the Guidances**

| Docket No. | Lead Center | Title of Guidance |
| --- | --- | --- |
| FDA-2020-D-1137 | **CBER** | Emergency Use Authorization for Vaccines to Prevent COVID-19 |
| FDA-2020-D-1825 | **CBER** | Investigational COVID-19 Convalescent Plasma |
| FDA-2015-D-1211 | **CBER** | Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products |
| FDA-2020-D-1137 | **CBER** | Development and Licensure of Vaccines to Prevent COVID-19 |
| FDA-2020-D-1137 | **CBER** | Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency |
| FDA-2020-D-1106-0002 | **CDER** | FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency |
| FDA-2020-D-1370 | **CDER** | COVID-19: Developing Drugs and Biological Products for Treatment or Prevention |
| FDA-2020-D-2016 | **CDER** | Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the COVID-19 Public Health Emergency (COVID-19) |
| FDA-2020-D-1136 | **CDER** | COVID-19: Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS-CoV-2 Infectivity |
| FDA-2020-D-1824 | **CDER** | Assessing COVID-19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment |
| FDA-2020-D-1414 | **CDER** | Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID-19 Public Health Emergency Guidance for IRBs and Clinical Investigators |
| FDA-2020-D-1057 | **CDER** | Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act Guidance for Industry |
| FDA-2021-D-0409 | **CDER** | COVID-19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention |
| FDA-2020-D-1136 | **CDER** | Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency Guidance for Industry |
| FDA-2020-D-1136 | **CDER** | COVID-19 Container Closure System and Component Changes: Glass Vials and Stoppers Guidance for Industry |
| FDA-2020-D-1136 | **CDER** | Development of Monoclonal Antibody Products Targeting SARS-CoV-2, Including Addressing the Impact of Emerging Variants, During the COVID 19 Public Health Emergency |
| FDA-2020-D-1138 | CDRH | Enforcement Policy for Face Masks and Barrier Face Coverings During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency |
| 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 (Revised) |
| FDA-2020-D-1138 | CDRH | Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency |
| FDA-2020-D-1138 | CDRH | Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) |
| 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 |
| FDA-2020-D-1108 | CFSAN | Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency |
| FDA-2020-D-1304 | CFSAN | Temporary Policy Regarding Accredited Third-Party Certification Program Onsite Observation and Certificate Duration Requirements During the COVID-19 Public Health Emergency |
| FDA-2020-D-1140 | CVM | CVM GFI #271 Reporting and Mitigating Animal Drug Shortages during the COVID-19 Public Health Emergency |