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.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993–0002, 240–402–7930.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 1, 2020 (85 FR 33169), FDA published a notice with a 90-day comment period to solicit comments on the listing of patent information in the FDA publication, ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (commonly known as the ''Orange Book'').

The Agency has received a request for an extension of the comment period for the public docket in order to develop a response to the request for comment.

FDA has considered the request and is reopening the comment period for the public docket for 30 days, until November 16, 2020. The Agency believes that an additional 30 days will allow adequate time for interested persons to submit comments.

Dated: October 13, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–22969 Filed 10–15–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–D–1136 and FDA–2020–D–1106]

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 October 16, 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 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 address 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 guidances.

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.

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 that 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 guidances:

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–1136	CDER	Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID–19 Public Health Emergency Questions and Answers (August 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	Resuming Normal Drug and Biologics Manufacturing Operations During the COVID–19 Public Health Emergency (September 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 September 2020).	*Clinicaltrialconduct-COVID19@fda.hhs.gov.* Please include the docket number FDA–2020–D–1106 and complete title of the guidance in the request.

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

[1] On April 21, 2020, the PHE Determination was extended, effective April 26, 2020; on July 23, 2020, it was extended, effective July 25, 2020; on October 2, 2020, it was extended, effective October 23, 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 (Mar. 13, 2020), available at *https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.*

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

CDER Guidances

The guidances listed in the table below refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for these guidances. However, these previously approved 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 2—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).
Guidance for Industry: Resuming Normal Drug and Biologics Manufacturing Operations During the COVID–19 Public Health Emergency.	21 CFR 210 and 211, 21 CFR 514.80, 21 CFR 600.	—Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients. —Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products. —Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act. —Reporting and Mitigating Animal Drug Shortages During the COVID–19 Public Health Emergency.	0910–0001, 0910–0032, 0910–0139, 0910–0338, 0910–0669, 0910–0675, 0910–0759, 0910–0806.
Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID–19 Public Health Emergency; Questions and Answers.	21 CFR 314.50; 314.95, 314.125, 314.127; 601.2 and 601.20.	—Prioritization of the Review of Original ANDAs, Amendments, and Supplements. —Requests for Expedited Review of New Drug Application and Biologics License Application Prior Approval Supplements Submitted for Chemistry, Manufacturing, and Controls Changes. —Administrative Processing of Original Biologics License Applications (BLA) and New Drug Applications (NDA). —Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products. —Changes to an Approved Application: Biological Products. —Changes to an Approved NDA or ANDA; Questions and Answers. —Changes to an Approved NDA or ANDA. —CMC Postapproval Manufacturing Changes To Be Documented in Annual Reports. —Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture. —CMC Postapproval Manufacturing Changes for Specified Biological Products To Be Documented in Annual Reports. —Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products. —Immediate Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation. —SUPAC–IR: Questions and Answers about SUPAC–IR Guidance. —Nonsterile Semisolid Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation. —SUPAC–MR: Modified Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation.	0910–0001, 0910–0014, 0910–0338, 0910–0045, 0910–0139, 0910–0759.

TABLE 2—CDER GUIDANCES AND COLLECTIONS—Continued

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance title referenced in COVID–19 guidance	OMB control No(s).
		—SUPAC: Manufacturing Equipment Addendum.	

The guidance listed in the table below refers to previously approved FDA collections of information. Therefore, clearance by OMB under the PRA is not required for this guidance. However, these collections of information are subject to review by OMB under the PRA. The previously approved 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 collection of information not approved under a current collection. This 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—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).	Collection covered by PHE PRA waiver
Guidance on Conduct of Clinical Trials of Medical Products during COVID–19 Public Health Emergency (Updated September 21, 2020).	21 CFR part 11, 21 CFR part 50, 21 CFR part 56, 21 CFR part 312, 21 CFR part 314, 21 CFR part 320, 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 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..	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.

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: October 13, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–22968 Filed 10–15–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2031]

Quality Management Maturity for Finished Dosage Forms Pilot Program for Domestic Drug Product Manufacturers; Program Announcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency), Center for Drug Evaluation and Research (CDER) is announcing its Quality Management Maturity for Finished Dosage Forms Pilot Program (QMM FDF Pilot Program) for domestic drug product manufacturers of prescription and over-the-counter (OTC) drug products. The purpose of the QMM FDF Pilot Program is to gain insight from third-party assessments of a manufacturer's quality management system to inform future development of an FDA rating system to characterize quality management maturity (QMM). Such a rating system would allow a cross-sectional comparison of manufacturers. Manufacturers that choose to disclose their facility ratings could benefit from a competitive advantage, as knowledge of QMM ratings would enable health systems and other purchasers and payers of medications to differentiate among drug manufacturers. This notice invites manufacturers that are interested in participating in the QMM FDF Pilot Program to submit a request to participate.

DATES: FDA will accept requests to participate in the QMM FDF Pilot Program through November 30, 2020, and the QMM FDF Pilot Program will run through December 31, 2021. See the ''Participation'' section for selection criteria and instructions on how to submit a request to participate.

FOR FURTHER INFORMATION CONTACT: *For general questions about the QMM FDF Pilot Program:* Jennifer Maguire, Center for Drug Evaluation and Research (CDER), 10903 New Hampshire Ave., Silver Spring, MD 20993, Bldg. 51, Rm. 4134, 240–402–4817, *Jennifer.Maguire@fda.hhs.gov.*

To submit a request to participate in the QMM FDF Pilot Program: Seongjin (Cindy) Pak, CDER, Bldg. 51, Rm. 4220, 301–796–1673, *Seongjin.Pak@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 2002, FDA launched an initiative, ''Pharmaceutical CGMPs for the 21st Century—A Risk-Based Approach,'' to enhance and modernize the regulation of pharmaceutical manufacturing and product quality.[1] One objective, among others, was to facilitate the implementation of a modern, risk-based pharmaceutical quality assessment system. The desired state has been described as a maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high-quality drug products without extensive regulatory oversight.

There has been significant progress toward this vision as evidenced by FDA programs and initiatives in such areas as pharmaceutical development and quality by design, quality risk management and pharmaceutical quality systems, process validation, and emerging technologies. These programs and initiatives promote use of the best pharmaceutical science and engineering principles throughout the product life cycle.

Another example is the FDA Quality Metrics Program, described in the November 2016 revised draft guidance for industry ''Submission of Quality Metrics Data'' (81 FR 85226). When final, this guidance will represent FDA's current thinking on this issue. In June 2018, FDA initiated two voluntary programs that sought additional industry input on quality metrics. FDA solicited industry participation for a Site Visit Program (83 FR 30751) for manufacturing establishments to present the advantages and challenges associated with implementing and managing a quality metrics program, and for a Quality Metrics Feedback Program (83 FR 30748) to engage stakeholders in identifying mutually useful and objective quality metrics.

The Agency continues to develop the FDA Quality Metrics Program but recognizes that quality metrics are only one element within a manufacturer's larger effort to increase the maturity of their quality management system. Manufacturers that demonstrate QMM operate under an enhanced quality management system that exceeds the minimum standards specified in current good manufacturing practice regulations and focuses on continual improvement. Characteristics of a mature quality management system include, for example, the ability to consistently and reliably deliver quality product over time, operational stability, and a strong quality culture. Additionally, for manufacturers with a mature quality management system, FDA can exercise a more flexible regulatory approach, leading toward the goal of producing high-quality drug products without extensive regulatory oversight.

A transparent method of evaluating and communicating QMM is needed to fully realize the 21st century pharmaceutical quality vision. Toward that end, FDA is announcing the start of the QMM FDF Pilot Program. Through this pilot program, a third-party contractor identified by FDA will conduct an assessment of a manufacturer's quality management system, accompanied by FDA staff. The Agency will gain insight from the results of the QMM assessments to inform the development of a rating system to measure and rate QMM. Assessments under the QMM FDF Pilot Program will cover multiple topics. Examples include but are not limited to:

1. Supply chain management;
2. manufacturing strategy and operations;
3. safety, environmental, and regulatory compliance;
4. inventory management;
5. performance management and continual improvement;
6. risk management;
7. management review and responsibility;
8. planning;
9. workforce management;
10. quality culture; and
11. customer experience.

In the same timeframe as the QMM FDF Pilot Program, FDA will conduct a QMM pilot program for foreign manufacturers of active pharmaceutical ingredients (APIs), including facilities manufacturing drug substance intermediates used to produce APIs. These pilot programs are funded separately and are intended to provide FDA with representative information about QMM from different types of drug manufacturers (API and FDF). Elsewhere in this issue of the **Federal Register,** FDA is publishing ''Quality Management Maturity for Active Pharmaceutical Ingredients Pilot Program for Foreign Facilities; Program Announcement.''

[1] See FDA's final report: ''Pharmaceuticals CGMPs for the 21st Century—A Risk-Based Approach'' (September 2004) at *https://www.fda.gov/media/77391/download.*