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 postings 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.


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**


**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-2015-09-08/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 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-2015-09-08/pdf/2015-23389.pdf.

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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. 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.

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>
<thead>
<tr>
<th>Docket No.</th>
<th>Center</th>
<th>Title of guidance</th>
<th>Contact information to request single copies</th>
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</table>

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 following COVID–19-related guidances:

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/PresidentialActions/Pages/default.aspx.
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 (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>
<thead>
<tr>
<th>COVID–19 guidance title</th>
<th>CFR cite referenced in COVID–19 guidance</th>
<th>Another guidance title referenced in COVID–19 guidance</th>
<th>OMB control No(s.)</th>
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### TABLE 2—CDER GUIDANCES AND COLLECTIONS—Continued

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<td>—SUPAC: Manufacturing Equipment Addendum.</td>
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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

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<td>Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans.</td>
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<td>Draft Guidance for Industry on Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products.</td>
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<td>Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Design.</td>
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<td>Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials.</td>
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### IV. Electronic Access

Persons with access to the internet may obtain COVID–19-related guidances at:

- the FDA web page entitled “Search for FDA Guidance Documents” available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents; or
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. 4220, 301–796–1673, Seongjin.Pak@fda.hhs.gov.

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 risk management. 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.”