

*Contains Nonbinding Recommendations*

**Good Manufacturing Practice  
Considerations for Responding to  
COVID-19 Infection in Employees in  
Drug and Biological Products  
Manufacturing**

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**Guidance for Industry**

June 2020

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Center for Biologics Evaluation and Research  
Center for Veterinary Medicine**

# Preface

## Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (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)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1136 and complete title of the guidance in the request.

## Additional Copies

Additional copies are available from the FDA web page titled "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>, and the FDA web page titled "Search for FDA Guidance Documents," *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an email request to [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov), [ocod@fda.hhs.gov](mailto:ocod@fda.hhs.gov), or [AskCVM@fda.hhs.gov](mailto:AskCVM@fda.hhs.gov) to receive an additional copy of the guidance. Please include the docket number FDA-2020-D-1136 and complete title of the guidance in the request.

## Questions

For questions about this document, contact (CDER) [CDER-OPQ-Inquiries@fda.hhs.gov](mailto:CDER-OPQ-Inquiries@fda.hhs.gov), (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010, or (CVM) [AskCVM@fda.hhs.gov](mailto:AskCVM@fda.hhs.gov).

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# **Good Manufacturing Practice Considerations for Responding to COVID-19 Infection in Employees in Drug and Biological Products Manufacturing**

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## **Guidance for Industry**

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

## **I. Introduction**

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide recommendations to drug and biological product manufacturers<sup>1,2</sup> regarding:

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<sup>1</sup> For purposes of this guidance, the term *drug manufacturer* is used herein to mean entities that make human or animal active pharmaceutical ingredients, prescription drugs, over-the-counter drugs, biological drug products, as well as drugs prepared by outsourcing facilities registered with FDA under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b) or compounding pharmacies regulated under section 503A of the FD&C Act (21 U.S.C. 353a).

<sup>2</sup> Drug products compounded by State-licensed pharmacies and Federal facilities that do not register with FDA as outsourcing facilities and that meet all of the conditions in section 503A of the FD&C Act, while not subject to current good manufacturing practice requirements, are subject to other provisions in the FD&C Act including section 501(a)(2)(A) (21 U.S.C. 351(a)(2)(A)). Accordingly, references throughout this guidance regarding the application of current good manufacturing practice requirements to drug manufacturers are not intended to address such compounding pharmacies. However, these compounders should implement additional controls and processes to prevent or correct insanitary conditions whereby drugs could become contaminated. This should include measures to prevent ill employees from compounding drugs and enhanced cleaning, sanitization, and if necessary, sterilization, of facilities and equipment.

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- Manufacturing controls to prevent contamination of drugs<sup>3</sup>
- Risk assessment of SARS-CoV-2 as it relates to drug safety or quality
- Continuity of manufacturing operations

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)). However, the recommendations described in the guidance are expected to assist the Agency more broadly in its continued efforts to assure the safety and quality of drugs and maintain the drug supply beyond the termination of COVID-19 public health emergency and reflect the Agency's current thinking on this issue. Therefore, within 60 days following the termination of the public health emergency, FDA intends to revise and replace this guidance with any appropriate changes based on comments received on this guidance and the Agency's experience with implementation.

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020 (85 FR 16949), titled "Process for Making Available Guidance Documents Related to Coronavirus Disease 2019," available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (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)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

## **II. Background**

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, HHS issued a declaration of a public health

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<sup>3</sup> For purposes of this guidance, the term *drug* or *drugs* as used throughout this guidance includes biological products.

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emergency related to COVID-19 and mobilized the Operating Divisions of HHS.<sup>4</sup> In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.<sup>5</sup>

COVID-19 disease is caused by SARS-CoV-2, a member of the corona family of viruses (Coronaviridae), which are single-stranded positive sense RNA (ss (+) RNA) viruses ranging from 120 to 160 nanometers in size.<sup>6</sup>

The preliminary results of recent research indicate the following regarding SARS-CoV-2:

- It is stable for several hours to days in aerosols and on surfaces<sup>7</sup>
- The incubation period of SARS-CoV-2 and other human coronaviruses such as SARS-CoV-1 and MERS-CoV is 2 to 14 days<sup>8</sup>

The Centers for Disease Control and Prevention (CDC) describes how COVID-19 spreads on their website.<sup>9</sup>

## **III. Manufacturing Controls to Prevent Contamination of Drugs**

Drug manufacturers are expected to prevent or mitigate potential adverse effects on the safety and quality of drugs from an infected or potentially infected employee engaged in drug manufacturing. During the COVID-19 public health emergency, drug manufacturers should review the following current good manufacturing practice (CGMP) regulations and recommendations regarding restriction of sick employees from production areas:

For drug products, 21 CFR 211.28(d), “Personnel responsibilities,” requires that:

Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drug products shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical

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<sup>4</sup> Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists (Jan. 31, 2020, renewed April 21, 2020), *available at* <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

<sup>5</sup> 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/>.

<sup>6</sup> PE Pellett, S Mitra, and TC Holland, 2014, Basics of Virology. In: AC Tselis, J Booss, editors, Handbook of Clinical Neurology, Elsevier B. V., Vol. 123.

<sup>7</sup> One limited study found that the virus remains viable in aerosols throughout a 3-hour test period, up to 4 hours on copper, up to 24 hours on cardboard, and 2 to 3 days on plastic and stainless steel (<https://www.nih.gov/news-events/news-releases/new-coronavirus-stable-hours-surfaces>).

<sup>8</sup> <https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html>

<sup>9</sup> <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html>

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personnel not to jeopardize the safety or quality of drug products. All personnel shall be instructed to report to supervisory personnel any health conditions that may have an adverse effect on drug products.

For active pharmaceutical ingredients (API), the ICH guidance for industry *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients* (September 2016), section III., Personnel (3),<sup>10</sup> recommends:

Personnel suffering from an infectious disease or having open lesions on the exposed surface of the body should not engage in activities that could result in compromising the quality of APIs. Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions should be excluded from activities where the health condition could adversely affect the quality of the APIs until the condition is corrected or qualified medical personnel determine that the person's inclusion would not jeopardize the safety or quality of the APIs.

For positron emission tomography (PET) drugs, 21 CFR 212.30, "What requirements must my facilities and equipment meet?," states:

(a) Facilities. You must provide adequate facilities to ensure the orderly handling of materials and equipment, the prevention of mix-ups, and the prevention of contamination of equipment or product by substances, personnel, or environmental conditions that could reasonably be expected to have an adverse effect on product quality.

For biological products, 21 CFR 600.10(c)(1), "Restrictions on personnel – (1) Specific duties," states:

Persons whose presence can affect adversely the safety and purity of a product shall be excluded from the room where the manufacture of a product is in progress.

Drug manufacturers should vigilantly monitor employees who perform drug manufacturing functions<sup>11</sup> and have been exposed to others with confirmed or suspected COVID-19 for symptoms of COVID-19 infection.<sup>12</sup> Employees who (1) test positive for COVID-19 (regardless of whether they have symptoms) or (2) have symptoms of COVID-19 must be excluded from drug manufacturing areas in accordance with the applicable CGMP requirements referenced above. FDA recommends that such employees should not return to work in such areas until the

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<sup>10</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

<sup>11</sup> Drug manufacturers should be cognizant that employees not directly involved in drug manufacturing (e.g., office workers in other departments), but co-located in the same building as the manufacturing areas and suites, or even different buildings on the same campus, could infect manufacturing employees depending on opportunities for personnel contact.

<sup>12</sup> Drug manufacturers should be aware that other illnesses manifest similar symptoms (e.g., common cold, influenza) and determine the nature of the illness whenever possible. See CDC information regarding symptoms of coronavirus, available at <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>.

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CDC's criteria to discontinue home isolation are met, in consultation with health care providers.<sup>13</sup>

To ensure compliance with CGMP requirements, drug product manufacturers must ensure that employees practice good sanitation and health habits, in accordance with 21 CFR 211.28(b).<sup>14</sup> Additionally, FDA recommends that API manufacturers ensure that employees practice good sanitation and health habits as described in ICH Q7, section III.B., Personnel Hygiene (3.2). Drug manufacturers, including API manufacturers, should be aware that under section 501(a)(2) of the FD&C Act, a drug that is not manufactured, processed, packed, or held in conformity with current good manufacturing practice to assure that the drug meets certain quality and purity standards is considered adulterated.

In accordance with quality risk management principles,<sup>15</sup> drug manufacturers are expected to take the following steps to prevent or mitigate potential adverse effects on the safety and quality of drugs from an infected or potentially infected employee engaged in drug manufacturing:

- Evaluate the adequacy of the CGMP controls already in place to protect materials, components, drug container closures, in-process materials, and/or drugs from sick employees in the context of this new coronavirus. For example, review cleanroom process controls such as air filtration, positive air pressure and movement of air to ensure proper function. Consider the likelihood of contamination or cross-contamination to other drugs in the facility. Current microbiological controls, if strictly implemented (e.g., employees only work in area with closed system processing), may be sufficient to protect the drugs and materials used to make them from SARS-CoV-2 contamination. If needed, implement additional controls to eliminate or minimize the risk of contamination.
- For biological products where manufacturing processes or materials are more susceptible to viral contamination, manufacturers should already have stringent viral control strategies in place. Potential risks from SARS-CoV-2 are likely to be mitigated by existing viral control strategies. However, FDA recommends that manufacturers perform a risk assessment of the current viral control strategy in light of SARS-CoV-2 and implement appropriate mitigation strategies. This should include, but not be limited to, leveraging available information to assess:<sup>16</sup>
  - The potential for the production cell line to replicate SARS-CoV-2
  - Whether current cell bank and harvest testing for viruses (see the ICH guidance for industry *Q5A Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin* (September 1998)) would detect SAR-CoV-2

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<sup>13</sup> See <https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html>.

<sup>14</sup> See also 21 CFR 212.30; 21 CFR 600.10(c).

<sup>15</sup> See the ICH guidance for industry *Q9 Quality Risk Management* (June 2006).

<sup>16</sup> For some biological products, such as cellular and gene therapy products, there may be additional considerations for risk assessments and some of the factors mentioned above (e.g., the references to production cell line and viral clearance and inactivation steps) may not be applicable to those products.

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- The effectiveness of viral clearance and inactivation steps for SARS-CoV-2
- Controls in place for procedures taking place in open systems (e.g., buffer and media preparation areas)

During this COVID-19 public health emergency, drug manufacturers should review CGMP requirements and recommendations related to facility and equipment cleaning and sanitation and other controls that ensure materials, APIs, components, drug product containers and closures, in-process materials, and drug products are safe and meet their quality requirements.<sup>17</sup>

To help prevent transmission among employees and contamination of drugs/materials by a COVID-19-infected employee engaged in drug manufacturing at the workplace, drug manufacturers should:

- Clean and sanitize nonproduction areas (such as offices, elevators, break rooms, changing rooms, and restrooms) more frequently.
- Update existing procedures to institute more frequent cleaning, sanitization, and/or sterilization of surfaces in the production areas, particularly surfaces that are contacted frequently, such as door handles, equipment latches, bench/counter tops, and control panels. Special attention should be paid to sanitizing/sterilizing equipment and product-contact surfaces.
- Consider expanding existing procedures to include using gloves, face masks, and/or gowning where such measures were not previously required.
- Consider further restrictions on employee access to any manufacturing area, beyond that required by CGMP regulations and recommended by Agency guidance<sup>18</sup> and normal practice, to limit the possibility of contamination.

If a potential or actual viral contamination event is identified, drug manufacturers should promptly clean, disinfect, sanitize, and if necessary, sterilize affected equipment, surfaces, production areas, and facilities, before resuming manufacturing.

If supplies of single-use masks and other garb used to control contamination during manufacturing are low, they should be prioritized for use in sterile manufacturing operations. To mitigate supply issues, drug manufacturers may need to re-sterilize or disinfect masks and garb, as appropriate, and reuse them during non-sterile drug operations. FDA intends to post policies

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<sup>17</sup> For example, other relevant CGMPs include but are not limited to 21 CFR 211.56, 21 CFR 211.67, 21 CFR 211.113, and 21 CFR 211.80. See also ICH Q7, section IV., Buildings and Facilities (4), section V.B., Equipment Maintenance and Cleaning (5.2), and section VII., Materials Management (7). For PET drugs, relevant CGMPs include but are not limited to 21 CFR 212.20, 21 CFR 212.50, and 21 CFR 212.70.

<sup>18</sup> See 21 CFR 211.28(c), 21 CFR 212.30, and ICH Q7, section IV.A., Design and Construction, paragraph (4.13).

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on disinfection or re-sterilization methods for use during the COVID-19 public health emergency on its website when available.<sup>19</sup>

To ensure compliance with CGMP requirements, drug product manufacturers must ensure that all evaluations of the production controls (including risk assessments), follow-up, and changes are approved by the manufacturer's quality unit and documented within the manufacturer's quality management system, in accordance with 21 CFR 211.22, 21 CFR 211.100, and 21 CFR 212.20. (See also 21 CFR 211.113.) Additionally, FDA recommends that API manufacturers have procedures in place to ensure that all evaluations of production controls (including risk assessments), follow-up, and changes are approved by the manufacturer's quality unit and documented within the manufacturer's quality management system (see ICH Q7, section II., Quality Management, and section XIII., Change Control). Drug manufacturers, including manufacturers of API, should be aware that under section 501(a)(2) of the FD&C Act, a drug that is not manufactured, processed, packed, or held in conformity with current good manufacturing practice to assure that the drug meets certain quality and purity standards is considered adulterated.

## **IV. COVID-19 Impact on Drug Safety, Quality, and Disposition**

FDA is not aware of any drugs that have been contaminated with SARS-CoV-2 or of information indicating transmission of COVID-19 is associated with drugs. However, SARS-CoV-2 is a novel coronavirus and, to ensure compliance with CGMP requirements, drug manufacturers are expected to evaluate whether it poses new risks in the context of their specific drugs, facilities, processes, and manufacturing controls. Drug manufacturers should determine if SARS-CoV-2 could adversely affect the safety or quality of their materials, components, drug product containers and closures, in-process materials, and drugs if they were to become contaminated with the virus. The risk assessment should consider the known characteristics and studies of this family of viruses as well as the drug types and their characteristics (e.g., drug product or API, sterile, non-sterile, solids, powders, liquids, large or small molecule).

Lots or batches of components, drug product containers and closures, in-process materials, and/or drug products determined to be adversely affected in terms of safety and quality must not

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<sup>19</sup> See the following guidances for industry and Food and Drug Administration staff: *Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* (March 2020) and *Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)* (April 2020). See also the guidance for industry *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 2020). Check the COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders web page periodically at <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders> for additional relevant guidances as they become available.

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be released for further manufacturing or for distribution.<sup>20</sup> Such items must be properly dispositioned (e.g., quarantined pending appropriate re-evaluation or reprocessing, or rejected).<sup>21</sup>

Lots or batches of APIs determined to be adversely affected in terms of safety or quality must not be distributed.<sup>22</sup> Such lots or batches should be properly dispositioned (e.g., quarantined pending appropriate re-evaluation or reprocessing, or rejected).<sup>23</sup>

To ensure compliance with CGMP requirements, drug product manufacturers must ensure that all evaluations (including risk assessments) to determine if drug safety or quality were adversely affected, as well as any follow-up and changes, are approved by the manufacturer's quality unit and documented within the manufacturer's quality management system, in accordance with 21 CFR 211.22, 21 CFR 211.100, and 21 CFR 212.20. Additionally, FDA recommends that API manufacturers have procedures in place to ensure that all evaluations to determine if API safety or quality were adversely affected, as well as any follow-up and changes, are approved by the manufacturer's quality unit and documented within the manufacturer's quality management system (see ICH Q7, section II., Quality Management, and section XIII., Change Control).

## **V. Maintaining the Drug Supply**

During this outbreak drug manufacturers may learn that an employee(s) has tested positive for COVID-19 or has been exposed to a person having the COVID-19 infection. Such an employee may or may not be symptomatic. To ensure compliance with CGMP requirements, manufacturers should direct workers who have symptoms (e.g., fever, cough, or shortness of breath) to notify their supervisors and stay home.<sup>24</sup> The CDC has issued guidance regarding steps sick workers can take to help prevent the spread of COVID-19.<sup>25</sup>

Manufacturers should also direct workers who have been exposed or potentially exposed to COVID-19 at work, home, or elsewhere to notify their supervisors. Workers at drug manufacturers have been deemed essential critical infrastructure workers during the COVID-19 public health emergency.<sup>26</sup> The CDC has issued guidance regarding when critical infrastructure workers may continue working following exposure or potential exposure to COVID-19. For more information, drug manufacturers should consult CDC guidance *Implementing Safety Practices for Critical Infrastructure Workers Who May Have Had Exposure to a Person with Suspected or Confirmed COVID-19*.<sup>27</sup> During this COVID-19 outbreak, drug manufacturers

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<sup>20</sup> See 21 CFR 211.89, 21 CFR 211.165(f), 21 CFR 211.115, and 21 CFR 212.20.

<sup>21</sup> See 21 CFR 211.80(d), 21 CFR 211.110(d), 21 CFR 211.165(f), and 21 CFR 212.71.

<sup>22</sup> See section 501(a)(2) of the FD&C Act.

<sup>23</sup> See also ICH Q7, section VII., Materials Management (7), and section XIV., Rejection and Re-Use of Materials (14).

<sup>24</sup> <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html>

<sup>25</sup> Ibid.

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[https://www.cisa.gov/sites/default/files/publications/Version\\_3.0\\_CISA\\_Guidance\\_on\\_Essential\\_Critical\\_Infrastructure\\_Workers\\_1.pdf](https://www.cisa.gov/sites/default/files/publications/Version_3.0_CISA_Guidance_on_Essential_Critical_Infrastructure_Workers_1.pdf)

<sup>27</sup> <https://www.cdc.gov/coronavirus/2019-ncov/community/critical-workers/implementing-safety-practices.html>

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should consider implementing social distancing procedures in accordance with CDC guidelines for employers to minimize exposure and transmission.<sup>28</sup>

In addition to taking steps to prevent adverse effects of employees infected with COVID-19 on the safety and quality of drugs, drug manufacturers of medically necessary human drugs should also implement contingency production plans if COVID-19 infections result in high absenteeism at drug manufacturing facilities during this public health crisis. See the guidance for industry *Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products* (March 2011). If the data and record management system supports it, drug manufacturers can consider permitting quarantined and recovering employees to work remotely on certain manufacturing functions that could be handled off-site (e.g., batch record and analytical record review and investigations).

If steps taken to prevent or mitigate adverse effects on safety and quality of drugs (e.g., rejected lots or recalls) are likely to lead to a disruption in the drug supply, drug manufacturers of human drugs should immediately contact FDA. For drugs regulated by the Center for Drug Evaluation and Research (CDER), drug manufacturers should submit notification either via email at [drugshortages@fda.hhs.gov](mailto:drugshortages@fda.hhs.gov) or through the CDER NextGen Portal at <https://edm.fda.gov/wps/portal/>. For drugs regulated by the Center for Biologics Evaluation and Research, drug manufacturers should submit notification electronically via email at [cbershorage@fda.hhs.gov](mailto:cbershorage@fda.hhs.gov). Contacting FDA allows drug manufacturers to meet any obligations to report discontinuances or interruptions in their manufacturing of drugs under section 506C of the FD&C Act (21 U.S.C. 356c)<sup>29</sup> and 21 CFR 314.81(b)(3)(iii). To report shortages for animal drugs, contact the Center for Veterinary Medicine at [AnimalDrugShortages@fda.hhs.gov](mailto:AnimalDrugShortages@fda.hhs.gov).<sup>30</sup>

The CDC, HHS, and the Occupational Safety and Health Administration (OSHA) have provided more expansive recommendations regarding overall strategies employers can employ to manage COVID-19 in the workplace. See CDC's website for more information and links to OSHA and HHS guidance. Also, the Environmental Protection Agency's (EPA's) list of disinfectants for use against SARS-CoV-2 virus may be useful. Drug manufacturers are encouraged to review the following resources for more information during the COVID-19 public health emergency:

- CDC web page Businesses and Workplaces: Plan, Prepare, and Respond (<https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/businesses-employers.html>)
- CDC document "Keeping the Workplace Safe" (<https://www.cdc.gov/coronavirus/2019-ncov/downloads/workplace-school-and-home-guidance.pdf>)
- CDC web page How to Protect Yourself & Others (<https://www.cdc.gov/coronavirus/2019-ncov/prepare/prevention.html>)

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<sup>28</sup> <https://www.cdc.gov/coronavirus/2019-ncov/community/general-business-faq.html>

<sup>29</sup> See the guidance for industry *Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act* (March 2020).

<sup>30</sup> See the guidance for industry *Reporting and Mitigating Animal Drug Shortages during the COVID-19 Public Health Emergency* (May 2020).

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- CDC web page Interim Guidance for Businesses and Employers Responding to Coronavirus Disease 2019 (COVID-19) (<https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html>)
- EPA web page List N: Disinfectants for Use Against SARS-CoV-2 (<https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>)
- OSHA document “Guidance on Preparing Workplaces for COVID-19” (<https://www.osha.gov/Publications/OSHA3990.pdf>)