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COVID-19 Public Health Emergency: Policy on COVID-19-Related Sanitation Tunnels

Guidance for Industry and Investigators

February 2022

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

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 e-mail request to COVID19-productdevelopment@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number FDA-2020-D-1136 and complete title of the guidance in the request.

Questions

For questions about this document, contact Kristen Leazer, Consumer Safety Officer, Division of Nonprescription Drugs II, kristen.leazer@fda.hhs.gov, (240) 402-1418.

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Guidance for Industry and Investigators

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.

Because of significant concerns for human safety, FDA is issuing this guidance to discourage sponsors from developing or seeking approval or authorization for the use of sanitation tunnels, also known as disinfection tunnels or sanitizing tunnels. Sanitation tunnels are tunnels, walkways, chambers, and similar systems that use sensor-based nozzles to spray humans (and their clothing) with a mist of disinfectant or aerosolized antiseptic as they walk or ride through

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these tunnels.^{1,2,3,4,5,6,7} First installed in China, these tunnels have been developed in countries outside of the United States with the aim of treating or reducing the spread of COVID-19. Sanitation tunnels are generally located outside crowded places such as food markets, shopping malls, hospitals, police stations, airports and train stations, offices, and industrial complexes.

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).

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, 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.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations,

¹ Biswal M, R Kanaujia, A Angrup, P Ray, S Mohan Singh, 2020, Disinfection Tunnels: Potentially Counterproductive in the Context of a Prolonged Pandemic of COVID-19, *Public Health*, 183:48–49.

² Sengupta R, 2020, Explained: What Are Disinfection Tunnels and Are They Safe? *Outlook*, accessed October 19, 2021, <https://www.outlookindia.com/website/story/india-news-explained-what-are-disinfection-tunnels-and-are-they-safe/350364>.

³ To Fight Coronavirus, Disinfectant Tunnel in China Sprays Industrial Workers, *US News and World Report*, accessed October 19, 2021, <https://www.usnews.com/news/world/articles/2020-02-12/to-fight-coronavirus-disinfectant-tunnel-in-china-sprays-industrial-workers>.

⁴ Bradshaw L, 2020, “Disinfection Tunnels” and “Safe Cabins” Introduced at Supermarkets, *The Bulletin*, accessed October 19, 2021, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7200329/pdf/main.pdf>.

⁵ Nayak, Y, 2020, Smart Disinfection and Sanitation Tunnel, *Hackster.io*, accessed October 19, 2021, <https://www.hackster.io/yugn27/smart-disinfection-and-sanitation-tunnel-aefe50>.

⁶ Palmer M and D Barth, 2020, Chinese Cities Are Rolling Out Disinfectant Tunnels and Spray Trucks to Ward Off the Coronavirus – But Experts Don’t Think It Will Work, *Business Insider India*, accessed October 19, 2021, <https://www.businessinsider.in/science/news/chinese-cities-are-rolling-out-disinfectant-tunnels-and-spray-trucks-to-ward-off-the-coronavirus-160but-experts-dont-think-it-will-work/articleshow/74305925.cms>.

⁷ Blust K, 2020, Cities in Mexico Use “Sanitation Tunnels” Despite Warnings From Health Professionals, *NPR*, accessed October 19, 2021, available at <https://www.npr.org/2020/05/21/860475339/cities-in-mexico-use-sanitation-tunnels-despite-warnings-from-health-professiona>.

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unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidance means that something is suggested or recommended, but not required.

II. BACKGROUND AND DISCUSSION

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 emergency related to COVID-19 and mobilized the Operating Divisions of HHS.⁸ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.⁹

FDA is aware of interest in approval or authorization of sanitation tunnels and similar products to prevent COVID-19 or other respiratory infections by spraying humans with a mist of disinfectant or aerosolized¹⁰ antiseptic. Sanitation tunnels are new drugs for which approved applications are required for marketing.¹¹ There is no evident basis under the FD&C Act under which sanitation tunnels can be legally marketed without an approved application.

As outlined in greater detail below, given the serious safety concerns and the lack of data to demonstrate that sanitation tunnels are effective in reducing the spread of SARS-CoV-2 infection

⁸ Secretary of Health and Human Services, Determination that a Public Health Emergency Exists. (originally issued January 31, 2020, and subsequently renewed), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

⁹ Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (March 13, 2020), available at <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>. On February 24, 2021, there was a Presidential Declaration continuing the national emergency concerning the COVID-19 pandemic beyond March 1, 2021. See Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) Pandemic (February 24, 2021), available at <https://www.federalregister.gov/documents/2021/02/26/2021-04173/continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic>.

¹⁰ For the purposes of this guidance, *aerosolization* means dispersion in air of a liquid material or a solution in the form of a fine mist.

¹¹ Generally, a drug is considered a *new drug* under section 201(p) of the FD&C Act (21 U.S.C. 321(p)) if it is not generally recognized as safe and effective (GRASE) under the conditions prescribed, recommended, or suggested in labeling. Under section 505G of the FD&C Act, certain nonprescription drugs marketed without an approved application may be legally marketed if they meet certain requirements, including the conditions of an applicable over-the-counter monograph. These sanitation tunnels do not fall under any applicable over-the-counter monograph, and FDA is not aware of any adequate and well-controlled clinical trials in published literature that support a determination that a sanitation tunnel is GRASE for use in reducing the spread of SARS-CoV-2 infection or in treating COVID-19. Moreover, there is no evident basis under the FD&C Act under which sanitation tunnels can be legally marketed without an approved application. Accordingly, sanitation tunnels are new drugs under section 201(p) of the FD&C Act (21 U.S.C. 321(p)) for which approved applications under section 505 of the FD&C Act (21 U.S.C. 355) are required for marketing.

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or in treating COVID-19, FDA strongly discourages the use or development of sanitation tunnels at this time.¹²

The Centers for Disease Control and Prevention (CDC) states that “aerosolizing any disinfectant can irritate the skin, eyes, or airways and can cause other health issues for people who breathe it in.”¹³ In addition, airway irritation could cause coughing that may facilitate the transmission of SARS-CoV-2.¹⁴

Furthermore, certain products that may be appropriate for use as directed can raise significant safety and other concerns when used in a sanitation tunnel, which are discussed in this guidance below. Surface disinfectants are not intended or labeled for use in humans or animals and should not be sprayed on humans or animals.¹⁵ Rather, surface disinfectants are intended for use on hard, nonporous surfaces.¹⁶ The CDC warns not to “eat, drink, breathe, or inject cleaning and disinfection products into your body or apply directly to your skin” because “[t]hey can cause serious harm.”¹⁷ In addition, some disinfectant chemicals, such as bleach (sodium hypochlorite), may trigger asthma attacks, and should not be used in enclosed spaces.¹⁸

¹² This guidance does not apply to systems that are intended for use in the cleaning, sterilization, or disinfection of medical devices. For further information, refer to the FDA guidance for industry *Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* (March 2020). 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>.

¹³ Safety Precautions When Using Electrostatic Sprayers, Foggers, Misters, or Vaporizers for Surface Disinfection During the COVID-19 Pandemic (April 14, 2021), available at <https://www.cdc.gov/coronavirus/2019-ncov/php/eh-practitioners/sprayers.html>.

¹⁴ The CDC has stated COVID-19 spreads when an infected person breathes out droplets and very small particles that contain the SARS-CoV-2 virus. According to the CDC, one of the three main ways COVID-19 spreads is when “these small droplets and particles that contain virus land on the eyes, nose, or mouth, especially through splashes and sprays like a cough or a sneeze.” See CDC’s COVID-19 Frequently Asked Questions, accessed December 15, 2021, available at <https://www.cdc.gov/coronavirus/2019-ncov/faq.html#Spread>.

¹⁵ See, for example, CDC, *Cleaning and Disinfecting Your Facility*, accessed December 15, 2021, available at <https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html> (warning against wiping or bathing people or pets with any surface cleaning and disinfection products).

¹⁶ The CDC has provided information regarding disinfectant practices for surfaces in the *Reopening Guidance for Cleaning and Disinfecting Public Spaces, Workplaces, Businesses, Schools, and Homes*, accessed January 24, 2022, which is available at <https://stacks.cdc.gov/view/cdc/87297>. In this document, CDC recommends paying “special attention to the personal protective equipment (PPE) that may be needed to safely apply the disinfectant.”

¹⁷ See CDC, *COVID-19 information on Cleaning and Disinfecting Your Facility*, accessed January 24, 2022, available at <https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html>.

¹⁸ CDC, *COVID-19 information for People with Moderate to Severe Asthma*, accessed January 24, 2022, <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/asthma.html>.

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Human antiseptic drugs, including hand sanitizers, can be legally marketed for use on human skin but are not intended for aerosolization.¹⁹ Hand sanitizers are intended for use only on the hands and should not be used over larger body surfaces, ingested, inhaled, or injected. On June 16, 2021, FDA warned that symptoms such as headache, nausea, and dizziness can occur after applying alcohol-based hand sanitizers to the skin.²⁰ These symptoms are likely to have occurred after inhaling vapors from the hand sanitizer, potentially from exposure in enclosed spaces or spaces with poor air circulation. On November 2, 2021, FDA warned that getting alcohol-based hand sanitizer in the eyes can result in serious eye injuries, including severe irritation and corneal abrasions.²¹ We have received numerous reports of these side effects since the start of the COVID-19 pandemic. Although most people experienced minor or minimal effects, some cases required treatment by a health care professional. The risk of both inhalational toxicity and ocular injury may be greater with an aerosolized drug product than with a product applied to the hands.

In addition, there are concerns regarding a person's ability to adequately review product labeling, including important safety information, and consent to treatment before walking through a sanitation tunnel. There are also concerns regarding unnecessary exposure of other persons (those not using the sanitation tunnel) to the drug, for example, via drug residue on sanitation tunnel users' clothing and personal effects, or nonusers being exposed to aerosolized droplets of the product outside of the sanitation tunnel.

Given the serious safety and other concerns outlined above and the lack of data to demonstrate that sanitation tunnels are effective in reducing the spread of SARS-CoV-2 infection or in treating COVID-19, FDA strongly discourages the use or development of sanitation tunnels at this time.

If, despite the significant safety and other concerns identified in this guidance, sponsors are interested in developing sanitation tunnels, FDA recommends that sponsors submit a pre-investigational new drug application meeting request for COVID-19 drug development.²² In a meeting package, sponsors should address the concerns described in this guidance and how the proposed study design will ensure that human subjects are not exposed to an unreasonable and significant risk of illness or injury. Given the significant safety and other concerns identified in this guidance, FDA may place an investigational new drug application to study sanitation tunnels on clinical hold (21 CFR 312.42). In preparation for a meeting with FDA, sponsors should also provide a statistical analysis plan to evaluate the efficacy of sanitation tunnels so that feasibility

¹⁹ See section 505G(a)(3) of the FD&C Act.

²⁰ FDA Drug Safety Communication. FDA warns that vapors from alcohol-based hand sanitizers can have side effects. Available at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-vapors-alcohol-based-hand-sanitizers-can-have-side-effects>.

²¹ FDA Drug Safety Communication. FDA warns that getting alcohol-based hand sanitizer in the eyes can cause serious injury. Available at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-getting-alcohol-based-hand-sanitizer-eyes-can-cause-serious-injury>.

²² See the guidance for industry and investigators *COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products* (May 2020).

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of the studies can be appropriately assessed. Sponsors engaged in developing drugs for the treatment or prevention of COVID-19 should also refer to FDA's COVID-19 web page for additional guidance documents.²³

²³ See COVID-19 guidance documents, available at <https://www.fda.gov/emergency-preparedness-andresponse/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-otherstakeholders>.