Availability of Rapid COVID–19 Testing

Since the March 20, 2020 Order, rapid testing for COVID–19 has been developed that can provide results in approximately 15 minutes and manufacturers are currently ramping up production and distribution of rapid COVID–19 testing.[21] Although rapid COVID–19 testing could ameliorate some of the public health concerns associated with congregate detention in DHS border facilities, rapid COVID–19 testing is not yet widely available, and demand outstrips supply. Moreover, once it is available, rapid COVID–19 testing should be prioritized to certain key locations, such as hospitals treating high numbers of COVID–19 patients, where the ability to quickly determine whether doctors and nurses have been infected with COVID–19 could increase the availability of care providers by eliminating the need for these individuals to self-isolate while awaiting test results.

Determination and Implementation

Based on the foregoing, I find that the global presence of COVID–19, including in Canada, Mexico, still presents a danger of further introduction of COVID–19 into the United States. This is true notwithstanding the community transmission of COVID–19 in many locations across the United States. There are many locations in the United States near our borders with Canada and Mexico that have not yet experienced widespread community transmission. The on-going COVID–19 pandemic, including in Canada and Mexico, remains a serious danger to such locations.

In the March 20, 2020 Order, I found the risks troubling partly because outbreaks of COVID–19 in POEs or Border Patrol stations would lead U.S. Customs and Border Protection to transfer persons with acute presentations of illness to local or regional healthcare providers for treatment, which would exhaust the local or regional healthcare resources or at least reduce the availability of such resources to the domestic population, and further expose local or regional healthcare workers to COVID–19. Millions of Americans are complying with local and state stay-at-home orders, engaging in social distancing, and taking other precautions calculated to slow the spread, protect others, and relieve the strain on the healthcare system. Their efforts would be significantly undermined if outbreaks of COVID–19 in land POEs or Border Patrol stations crippled the DHS workforce and local or regional healthcare systems.

I consulted with DHS before issuing this Order and requested that DHS continue to implement the March 20, 2020 Order because CDC does not have the capability, resources, or personnel needed to alternatively issue quarantine or isolation orders.[22]

The March 20, 2020 Order shall remain in effect until 11:59 p.m. EDT on May 20, or until I determine that the danger of further introduction of COVID–19 into the United Sates has ceased to be a serious danger to the public health, whichever is sooner. I may further amend or extend the March 20, 2020 Order as needed to protect the public health.

This Order is not a rule subject to notice and comment under the Administrative Procedure Act (APA). In the event this order qualifies as a rule subject to notice and comment, a delay in effective date are not required because there is good cause to dispense with prior public notice and the opportunity to comment on this order and a delay in effective date.[23] Given the public health emergency caused by COVID–19, it would be impracticable and contrary to the public health—and, by extension, the public interest—to delay the issuing and effective date of this order. In addition, because this order concerns ongoing discussions with Canada and Mexico on how to best control COVID–19 transmission over our shared borders, it directly ''involve[s] . . . a . . . foreign affairs function of the United States.'' 5 U.S.C. 553(a)(1). Notice and comment and a delay in effective date would not be required for that reason as well.

* * * * *

The March 20, 2020 Order shall remain in effect until 11:59 p.m. EDT on May 20, 2020.

Authority

The authority for these orders is Sections 362 and 365 of the Public Health Service Act (42 U.S.C. 265, 268) and 42 CFR 71.40.

Dated: April 19, 2020.

Robert K. McGowan,

Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2020–08605 Filed 4–20–20; 9:00 am]

BILLING CODE 4163–18–P

the COVID–19 Pandemic (Mar. 20, 2020), available at *https://www.dhs.gov/news/2020/03/20/joint-statement-us-mexico-joint-initiative-combat-covid-19-pandemic.*

[21] For instance, on March 27, 2020, Abbott received emergency use authorization from the U.S. Food and Drug Administration (''FDA'') for the fastest available point-of-care test for COVID–19. Abbott, ''Detect COVID–19 in as Little as 5 Minutes'' (Mar. 27, 2020), *https://www.abbott.com/corpnewsroom/product-and-innovation/detect-covid-19-in-as-little-as-5-minutes.html; see generally* U.S. Food and Drug Administration, Emergency Use Authorizations, *https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.* Rapid COVID–19 testing will significantly reduce the time needed to confirm a suspected diagnosis of COVID–19, which currently may take as long as three to four days. *See* CDC, Order Suspending Introduction of Certain Persons from Countries where a Communicable Disease Exists (Mar. 20, 2020), available at *https://www.cdc.gov/quarantine/pdf/CDC-Order-Prohibiting-Introduction-of-Persons_Final_3-20-20_3-p.pdf; see also* CDC, Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID–19) (updated Apr. 8, 2020), *https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html.* When a case of COVID–19 is suspected, the sooner that confirmatory test results are available, the more quickly treatment and isolation and quarantine measures can be implemented, lowering the risk of infecting others. *See* CDC, Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID–19) (updated Mar. 24, 2020), *https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html.*

[22] As previously discussed in the March 20, 2020 Order, CDC relies on the Department of Defense, other federal agencies, and state and local governments to provide both logistical support and facilities for federal quarantines. *See* 42 U.S.C. 268(b) (requiring customs officers to aid in the enforcement of quarantine regulations). CDC lacks the resources, staffing, and facilities to quarantine covered aliens. Similarly, DHS has informed CDC that in the near term, it is not financially or logistically practicable for DHS to build additional facilities at POEs and Border Patrol stations for purposes of quarantine or isolation.

[23] *See* 5 U.S.C. 553(b)(B) and (d)(3).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5573]

Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted Under a Biologics License Application, New Drug Application, or Abbreviated New Drug Application; Draft Guidance for Industry and Food and Drug Administration; 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 a draft guidance for industry and FDA entitled ''Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a BLA, NDA or ANDA.'' For injectable drug or biological products that are intended to treat emergent, life-threatening conditions, it is essential to ensure that the emergency-use injector will reliably deliver the drug or biological product as

intended. This is particularly critical for drugs when failure of the injector may prevent adequate delivery of a life-saving drug to a patient. The draft guidance describes the technical considerations for demonstrating reliability of emergency-use injectors under a biologics license application (BLA), new drug application (NDA), or abbreviated new drug application (ANDA).

DATES: Submit either electronic or written comments on the draft guidance by June 22, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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 Docket No. FDA–2019–D–5573 for ''Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a BLA, NDA or ANDA: Guidance for Industry and FDA.'' Received comments will be placed in the docket 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.

- 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia Love, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993, 301–796–8930, *patricia.love@fda.hhs.gov* or *combination@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA entitled ''Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a BLA, NDA or ANDA.'' For injectable drug or biological products that are intended to treat emergent, life-threatening conditions, it is essential to ensure that the injector will reliably deliver the drug or biological product as intended. This is particularly critical for drugs when failure of the emergency-use injector may prevent adequate delivery of a life-saving drug to a patient. This guidance's focus is emergency-use injectors marketed with the emergency-use drug/biological product as a prefilled single entity combination product or as a co-packaged combination product assigned to the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research with market authorization under an approved NDA, ANDA, or BLA.

The draft guidance describes the technical considerations for demonstrating reliability of emergency-use injectors under an NDA, ANDA, or BLA. For purposes of the draft guidance, reliability is defined as the probability that the injector will perform as intended, without failure, for a given time interval under specified conditions. The document describes information and data that FDA recommends be included in marketing applications to demonstrate that an emergency-use injector is reliable, including the details of an example of an acceptable approach for the mathematical model, statistics, fault tree analysis, and use of certain current good manufacturing practice requirements for combination products (21 CFR 4.4(b)(1)(ii) and (iv)) to establish reliability of the emergency-use injector.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

The draft guidance, when finalized, will represent the current thinking of FDA on ''Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a BLA, NDA or ANDA.'' 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.

II. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 for NDAs have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 for BLAs have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 814, subpart B, for premarket approval applications have been approved under OMB control number 0910–0231. The collections of information section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), subpart E for 510(k) notifications, have been approved under OMB control number 0910–0120. The collections of information in the guidance for industry and FDA staff entitled ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844. The collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/combination-products-guidance-documents* or *https://www.regulations.gov.*

Dated: April 16, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08466 Filed 4–21–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4711]

Nonbinding Feedback After Certain Food and Drug Administration Inspections of Device Establishments; Guidance for Industry and Food and Drug Administration Staff; 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 a final guidance entitled ''Nonbinding Feedback After Certain FDA Inspections of Device Establishments.'' FDA is issuing this guidance to comply with the FDA Reauthorization Act of 2017 (FDARA), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance identifies a standardized method for communicating and submitting requests for nonbinding feedback and describes how FDA evaluates and responds to such requests.

DATES: The announcement of the guidance is published in the **Federal Register** on April 22, 2020.

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 Docket No. FDA–2018–D–4711 for ''Nonbinding Feedback After Certain FDA Inspections of Device Establishments.'' Received comments will be placed in the docket 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.

- 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