



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Injectors Submitted Under a Biologics License Application, New Drug Application, or Abbreviated New Drug Application; Draft Guidance for Industry and Food and Drug Administration; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry and FDA entitled "Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a BLA, NDA or ANDA."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 The draft guidance describes the technical considerations for demonstrating reliability of emergency-use injectors under a biologics license application (BLA), new drug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DATES: Submit either electronic or written comments on the draft guidance by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** to

ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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.

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