DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 809

[Docket No. FDA–2024–D–0083]

Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration Under Section 564; Draft Guidance for Laboratory Manufacturers and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564.'' In the context of emergent situations involving chemical, biological, radiological, or nuclear (CBRN) threats, there may be a public health need for certain in vitro diagnostic devices (IVDs) to be available for immediate response purposes. When finalized, this guidance will describe the Agency's enforcement policy for certain laboratory manufacturers offering certain unauthorized IVDs for immediate response to CBRN agents in the absence of a declaration applicable to IVDs under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by July 5, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2024–D–0083 for ''Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564.'' 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, 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-2015-09-18/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.

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Toby Lowe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3416, Silver Spring, MD 20993–0002, 301–796–6512.

SUPPLEMENTARY INFORMATION:

I. Background

When finalized, this guidance will describe the Agency's enforcement policy for certain laboratory manufacturers offering certain unauthorized IVDs for immediate response to CBRN agents in the absence of a declaration applicable to IVDs under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (hereafter referred to as an ''applicable 564 declaration'').[1] In the context of

[1] The Office of the Federal Register has published this document under the category ''Proposed Rule''

emergent situations involving CBRN threats, there may be a public health need for certain IVDs to be available for immediate response purposes. An emergent situation is, for purposes of this guidance, the period of time between detection of the exposure or outbreak and, either, resolution of the exposure or outbreak or issuance of an applicable 564 declaration. In the past, during this period of time, laboratory manufacturers offered laboratory developed tests (LDTs) for which FDA has had a general enforcement discretion approach. However, as discussed in the preamble to the final rule amending FDA regulations to make explicit that IVDs are devices under the FD&C Act including when the manufacturer of the IVD is a laboratory (LDT Final Rule),[2] FDA is phasing out this general enforcement discretion approach for LDTs. Accordingly, FDA is issuing this guidance with our enforcement policy for ''immediate response'' tests.

This guidance, when finalized, will describe the Agency's enforcement policy for certain laboratory manufacturers offering certain unauthorized IVDs for immediate response to CBRN agents in the absence of an applicable 564 declaration. FDA does not intend to object to the offering of ''immediate response'' tests, as defined in the guidance, when the test is manufactured and offered by certain laboratory manufacturers, the test has been appropriately validated, FDA is notified, appropriate transparency is provided, the test is labeled for prescription use only, and there is no applicable 564 declaration, as described in the guidance. Prior to an emergent situation and after an emergent situation has been resolved, when there might not be a critical need for a coordinated and immediate public health response and where the implications of false results may not have as serious implications for public health decision-making, such tests may fall within the enforcement discretion policies described in section V.B of the preamble to the LDT Final Rule.

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 ''Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564.'' 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. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00007032 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part or guidance	Topic	OMB control No.
''Emergency Use Authorization of Medical Products and Related Authorities''.	Emergency Use Authorization	0910–0595
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
''Administrative Procedures for CLIA Categorization'' and ''Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''.	CLIA Administrative Procedures; CLIA Waivers	0910–0607
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485
803	Medical Device Reporting	0910–0437
810	Recalls	0910–0432

Dated: April 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08934 Filed 4–29–24; 8:45 am]

BILLING CODE 4164–01–P

pursuant to its interpretation of 1 CFR 5.9(b). We note that the categorization as such for purposes of publication in the **Federal Register** does not affect the content or intent of the document. See 1 CFR 5.1(c).

[2] ''Medical Devices: Laboratory Developed Tests'' is issued elsewhere in this **Federal Register**.