DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1115]

Agency Information Collection Activities; Proposed Collection; Comment Request; Emergency Use Authorization of Medical Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection activities related to emergency use authorization for medical products.

DATES: Either electronic or written comments on the collection of information must be submitted by September 12, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 12, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2025–N–1115] for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Emergency Use Authorization of Medical Products.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Emergency Use Authorization of Medical Products

OMB Control Number 0910–0595—Extension

This information collection helps support implementation of Agency policies applicable to the authorization for medical products for use in emergencies under sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b). For more information regarding emergency use authorization (EUA), visit our website at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.* The FD&C Act permits the Commissioner of Food and Drugs (the Commissioner) to authorize the use of unapproved medical products for humans and animals, or unapproved uses of approved medical products for humans and animals, during an emergency declared under section 564 of the FD&C Act. The data to support issuance of an EUA must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb–3(c)).

Also, under section 564 of the FD&C Act, the Commissioner may establish conditions on issuing an authorization that may be necessary or appropriate to protect the public health. These conditions can include: (1) requirements to disseminate or disclose information to healthcare providers or authorized dispensers and product recipients; (2) adverse event monitoring and reporting; (3) data collection and analysis; (4) specific recordkeeping and records access; (5) restrictions on product advertising, distribution, and administration; and (6) limitations on good manufacturing practice requirements. As governed by statute, some conditions are mandatory to the extent practicable for authorizations of unapproved products, and discretionary for authorizations of unapproved uses of approved products. Some conditions may apply to manufacturers of an EUA product, while other conditions may apply to any person who carries out an activity for which the authorization is issued. Sections 564A and 564B of the FD&C Act establish streamlined mechanisms intended to facilitate preparedness and response activities involving certain FDA approved products without requiring FDA to issue an EUA and set forth emergency dispensing order and expiration date extension authority.

The guidance document entitled, ''Emergency Use Authorization of Medical Products and Related Authorities'' (January 2017), available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities,* discusses FDA issuance of Emergency Use Authorizations (EUAs) under section 564 of the FD&C Act; implementation of the emergency use authorities set forth in section 564A of the FD&C Act; reliance on the governmental pre-positioning authority set forth in section 564B of the FD&C Act; and related FDA regulations. As discussed in the guidance document, the specific type and amount of data needed to support an EUA will vary depending on the nature of the declared emergency and the nature of the candidate product. The guidance document encourages early engagement with FDA, explains mechanisms for communication, and makes content and format recommendations on submitting information to the Agency. The guidance document also recommends that a request for consideration for an EUA include scientific evidence evaluating the product's safety and effectiveness, including the adverse event profile for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests for an EUA and/or a substantive amendment to an existing EUA:					
Center for Biologics Evaluation (CBER)	1	4	4	45	180
Center for Drug Evaluation and Research (CDER)	6	1	6		270
Center for Devices and Radiological Health (CDRH)	77	1.727	133		5,985
Total					6,435
Pre-EUA submissions or amendments:					
CBER	2	2	4	34	136
CDER	2	1	2		68
CDRH	23	1.4	32		1,088
Total					1,292
Submitting information required under conditions of authorization:					
CBER	4	3	12	8	96
CDER	8	5	40		320
CDRH	5	2.2	11		88
Total					504
State and local public health authority submissions required under conditions of authorization for unapproved EUA product; CBER, CDER and CDRH	1	1	1	2	2
State and local public health authority requests for Emergency Dispensing Order; CBER, CDER and CDRH	1	1	1	2	2

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
State and local public health authority requests for expiration date extension; CDER	1	1	1	20	20
Total					56,651

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Although we have averaged burden across all respondents, we categorize reporting activity by the type of EUA-related submission: (1) those who file a request for FDA to issue an EUA and/or a substantive amendment to an EUA that has previously been issued; (2) those who submit a request for FDA to review information/data (*i.e.,* a pre-EUA package) for a candidate EUA product or a substantive amendment to an existing pre-EUA package for preparedness purposes; (3) those who must report on activities related to an unapproved EUA product (*e.g.,* administering product, disseminating information) who must report to FDA regarding such activity; (4) public health authorities (*e.g.,* State, local) who must report on certain activities (*e.g.,* administering product, disseminating information) related to an unapproved EUA, and public health authorities who submit an expiration date extension request for an approved product; (5) those who request an emergency dispensing order under section 564A; and (6) those who request expiry dating extensions under section 564A of the FDC&C Act. We attribute greater burden to those requests for FDA to review pre-EUA packages submitted by product sponsors than burden we attribute to those submitted by Federal agencies (*e.g.,* Centers for Disease Control and Prevention, the Department of Defense), and have considered other factors that contribute to variability in burden for reporting, including the type of product and whether there is a previously reviewed pre-EUA package or investigational application.

We also account for burden that may be attendant to the use of the following agency EUA Templates and Fact Sheet Templates:

TABLE 2—EUA TEMPLATES AND FACT SHEET TEMPLATES

Template title	Date	Hyperlink
CDRH COVID–19 Diagnostic Templates (Molecular and Antigen)		
Molecular Diagnostic EUA Cover Sheet Template	10/06/2021	*https://www.fda.gov/media/152768/download?attachment.*
Molecular Diagnostic Template	10/06/2021	*https://www.fda.gov/media/135900/download?attachment.*
Molecular Diagnostic Home Specimen Collection Template	10/06/2021	*https://www.fda.gov/media/138412/download?attachment.*
Antigen Diagnostic Template	10/06/2021	*https://www.fda.gov/media/137907/download?attachment.*
Molecular and Antigen Home Use Test Template	11/09/2021	*https://www.fda.gov/media/140615/download?attachment.*
Supplemental Template for Molecular and Antigen Diagnostic COVID–19 Tests for Screening with Serial Testing.	10/25/2021	*https://www.fda.gov/media/146695/download?attachment.*
CDRH COVID–19 Serology/Antibody Templates		
Serology Template	10/06/2021	*https://www.fda.gov/media/137698/download?attachment.*
Template for Serology Tests that Detect or Correlate to Neutralizing Antibodies.	10/06/2021	*https://www.fda.gov/media/146746/download?attachment.*
CDRH COVID–19: Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS–CoV–2 Templates		
Appendix J—Sample Updated Fact Sheet for Health Care Providers.	04/20/2021	*https://www.fda.gov/media/147735/download?attachment.*
Appendix K—Sample Updated Fact Sheet for Patients	04/20/2021	*https://www.fda.gov/media/147736/download?attachment.*
CDRH COVID–19: Umbrella EUA for SARS–CoV–2 Molecular Diagnostic Tests for Serial Testing Templates		
Appendix L—Fact Sheet for Health Care Providers (Template)	11/15/2021	*https://www.fda.gov/media/154112/download?attachment.*
Appendix M—Fact Sheet for Patients (Template)	11/15/2021	*https://www.fda.gov/media/154114/download?attachment.*
Appendix N—Test Summary (Template)	11/15/2021	*https://www.fda.gov/media/154113/download?attachment.*
CDRH COVID–19: EUA for Molecular Diagnostic Tests for SARS–CoV–2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests Templates		
Fact Sheet for Healthcare Providers	11/15/2021	*https://www.fda.gov/media/136599/download?attachment.*
Fact Sheet for Patients	11/15/2021	*https://www.fda.gov/media/136600/download?attachment.*
CDRH Mpox Templates and EUA Summary Templates (Molecular and Antigen)		
EUA Summary Template for Developers of Molecular Diagnostic Tests for Monkeypox.	09/07/2022	*https://www.fda.gov/media/161447/download?attachment.*
EUA Template for Developers of Molecular Diagnostic Tests for Monkeypox.	09/07/2022	*https://www.fda.gov/media/161448/download?attachment.*

TABLE 2—EUA TEMPLATES AND FACT SHEET TEMPLATES—Continued

Template title	Date	Hyperlink
EUA Summary Template for Developers of Antigen Diagnostic Tests for Monkeypox.	11/29/2022	*https://www.fda.gov/media/163530/download?attachment.*
EUA Template for Developers of Antigen Diagnostic Tests for Monkeypox.	11/29/2022	*https://www.fda.gov/media/163529/download?attachment.*
CDRH Other Devices Templates		
Ventilator EUA Interactive Review Template	04/21/2020	*https://www.fda.gov/media/137172/download?attachment.*
CDER Therapeutics Fact Sheet Templates		
Healthcare Provider Fact Sheet Template	11/26/2024	*https://www.fda.gov/media/183876/download?attachment.*
Patient, Parent, and Caregiver Fact Sheet Template	11/26/2024	*https://www.fda.gov/media/183875/download?attachment.*

The CDRH templates are part of the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) and Policy for Monkeypox [mpox] Tests to Address the Public Health Emergency guidance documents, which also include additional policies specific to these public health emergencies. The templates reflect the FDA's current thinking on the data and information that developers should submit to facilitate the EUA process. The templates provide information and recommendations, and they are updated as appropriate as we learn more about the COVID–19 and mpox diseases and gain experience with the EUA process for the various types of tests. Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations to help them through the EUA process.

The CDER templates reflect the FDA's current thinking on the data and information that developers should include in the fact sheets for therapeutics. The templates provide general fact sheet information and recommendations. and are not specific to COVID–19. Developers who intend to use alternative approaches should consider seeking the FDA's feedback or recommendations during the EUA process. Members of the public can submit questions about the templates to *CDEREUA@fda.hhs.gov.*

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Records associated with conditions of authorization	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
EUA Holders:					
CBER	8	4	32	25	800
CDER	8	5	40		1,000
CDRH	668	2	1,336		33,400
Total					35,200
State and local Public Health Authorities; CBER, CDER and CDRH	1	1	1	3	3
Total					59,403

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We provide a conservative estimate for respondent recordkeeping, recognizing that the Federal Government performs much of this activity in conjunction with submissions. We do not include burden for public health authorities who may need to submit emergency dispensing orders or expiration date extension requests, assuming covered entities already maintain these records for the products they stockpile.

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Information collection activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Dissemination of required information by EUA Holder or Authorized Stakeholder:					
CBER	8	4	32	5	160
CDER	8	2	16		80
CDRH	668	2	1,336		6,680
Total					6,920

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our third-party disclosure estimate is based on the number of EUA holders and authorized stakeholders disseminating information, including fact sheets, advertising, and promotional materials.

Our estimated burden for the information collection reflects an overall decrease of 7,087 hours and a corresponding decrease of 302,456 responses.

Dated: July 8, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–13049 Filed 7–11–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–E–5424]

Determination of Regulatory Review Period for Purposes of Patent Extension; LAZCLUZE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for LAZCLUZE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see) are incorrect may submit either electronic or written comments and ask for a redetermination by September 12, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 12, 2026. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 12, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–E–5424 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; LAZCLUZE.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.'' TheAgency 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period