UNITED STATES FOOD & DRUG ADMINISTRATION

Emergency Use Authorization of Medical Products and Related Authorities

OMB Control Number 0910-0595

Terms of Clearance: The previous OMB approval included Terms of Clearance requiring FDA to seek comment on the EUA Fact Sheets. The agency solicited and reviewed public comment as required.

SUPPORTING STATEMENT **Part A – Justification:**

1. Circumstances Making the Collection of Information Necessary

This information collection helps support Food and Drug Administration (FDA, us or we, the agency) implementation of sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act) (21 U.S.C. 360bbb-3, 360bbb-3a, and 360bbb-3b), which govern the authorization of medical products for use in emergencies. The statutes authorize FDA to permit the introduction into interstate commerce *a drug, device, or biological product intended for use in an actual or potential emergency*. The purpose of these provisions is to sustain and strengthen national preparedness for public health, military, and domestic emergencies involving chemical, biological, radiological, and nuclear (CBRN) agents, including emerging infectious disease threats.

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.

We are therefore requesting extension of OMB approval for the information collection provisions set forth in sections 564, 564A, and 564, regarding the authorization of medical products for use in emergencies; in the implementing guidance document "*Emergency-Use-Authorization of Medical Products and Related Authorities*," and found in the referenced EUA templates, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We use information submitted under sections 564, 564A, and 564B of the FD&C Act to support the issuance of EUAs. Data used to support the issuance of an EUA must demonstrate, based on the totality of scientific evidence available to the Commissioner, including data from adequate and well controlled clinical trials, that it is reasonable to believe the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition. The information submitted also enables us to determine whether an eligible, FDA-approved product stockpiled for use in an emergency, is eligible for an extension of its expiration date under section 564A(b) of the FD&C Act, or whether criteria are met for an emergency dispensing order.

3. Use of Improved Information Technology and Burden Reduction

We estimate 95% of respondents will use electronic means to fulfill the information collection. Currently, most all submissions to the agency are required electronically under various authorities, unless an applicable waiver is granted that provides an exemption from the requirement. We provide technical assistance regarding submissions, available on our website and incorporated, as appropriate, into instructional information in forms and other submissions pertaining to product labeling and reporting. Submissions are made through our Electronic

Submissions Gateway (ESG). Device companies are instructed to submit one paper copy of a device application with an eCopy and identify the required format and technical requirements of the eCopy.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. While the referenced guidance recommends the maintenance of records specific to EUAs, we believe most recordkeeping burdens are already accounted for in OMB control nos. 0910-0139 and 0910-0073 for CGMPs for finished pharmaceuticals and finished devices, respectively; and OMB control no. 0910-0014 for IND application regulation.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection imposes undue burden on small entities. To ensure adequate protection of the public health, FDA's Office of Counterterrorism and Emerging Threats provides ongoing assistance on EUA issues to interested entities. Staff from the three medical product centers, the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH), consult with, and expend considerable resources providing technical assistance to, small businesses and other interested companies regarding pre-EUA and EUA submissions.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements. To conduct the collection less frequently would contravene mandates of the FD&C Act and increase risks to the public health during an actual or potential emergency.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The information collection is consistent with the guidelines in 5 CFR 1320.5(d)(2). However, as a condition of emergency use authorization, the FDA Commissioner may impose a specific reporting schedule based upon the risk-benefit profile of a particular EUA product.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice soliciting public comment in the *Federal Register* of July 14, 2025 (90 FR 31217). One comment was received. The comment did not discuss information collection activities related to emergency use authorization for medical products, was not responsive to the four information collection topics solicited, and did not offer information that would enable FDA to consider revising the information collection and/or burden estimates. Instead, the comment raised policy concerns about FDA's implementation of section 564 of the Federal Food, Drug and Cosmetic Act (21 USC 360bbb-3). Such comments may be offered to FDA through alternative means, such as directly to the FDA docket for the 2017 EUA guidance (which remains continually open for submissions) (FDA-

2016-D-1025) or through FDA's citizen petition process (21 CFR 10.30). Therefore, the comment will not be addressed in this document.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. While this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity).

Privacy Act

Conditions of authorization on an EUA could include use of a form, depending on the product and circumstances, i.e., Form FDA 2253 or MedWatch Form. The PII submitted via Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use) is name, address, telephone number, fax, and email address. MedWatch forms are Forms FDA 3500 (The FDA Safety Information and Adverse Event Reporting Program), FDA 3500A (For Use by User-Facilities and Manufacturers for Mandatory Reporting), and FDA 3500B (MedWatch, Consumer Voluntary Reporting). The PII submitted via Form FDA 3500 is patient identifier, date of birth, ethnicity, race, first name, last name, address, phone number, email address, and country. The PII submitted via Form FDA 3500A is patient identifier, date of birth, ethnicity, race, first name, last name, address, phone number, and email address. The PII submitted via Form 3500B is person's initials, first name, last name, address, telephone number, email address, country, date of birth, ethnicity, race, and gender. FDA determined that, although PII is collected, it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, we do not use name or any other personal identifier to routinely retrieve records from the information collected. Through appropriate form and webpage design, FDA limits submission fields and minimized the PII collected to protect the privacy of the individuals.

Freedom of Information Act

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature

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12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Reporting Burden[1]

Information Collection Activity	No. of Respondents	No. 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
State and local public health authority requests for expiration date extension; CDER	1	1	1	20	20
Total					24
Overall Total for Annual Reporting Burden					8,255

[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	04/20/2021	https://www.fda.gov/media/147736/download?attachment

Patients		
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
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	No. of Recordkeepers	No. 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					3
Overall Total for Annual Recordkeeping Burden					35,203

[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	No. of Respondents	No. 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.

The overall total annual burden for this ICR is 50,378 hours and 3,040 responses, representing the combined estimates for all reporting, recordingkeeping and third-party disclosure activities.

12b. Annualized Cost Burden Estimate

We assume an hourly wage rate of $97.00 (rounded)[1], including overhead and benefits, for employees in the private sector that prepare and submit information as described in this request. This figure is based on current data from the U.S. Bureau of Labor and Statistics (BLS) North American Industry Classification System (NAICS) for the occupational category of a compliance officer in Pharmaceutical and Medicine Manufacturing. For employees of state and local governments, we estimate an average hourly wage rate of $140.00 (rounded) per hour, including overhead and benefits. This estimate is based on the average hourly wage of a medical and health services manager employed by state or local governments derived from the BLS NAICS.

Table 4. – Respondent Costs

REPORTING: Respondent Labor Category	Annual Burden Hours	Hourly Wage Rate	Total Respondent Costs
Compliance Officer; Requests to Issue an EUA for an unapproved product or a Substantive Amendment to an Existing EUA	6,435	$97	$624,195
Compliance Officer; Request FDA Review of a Pre-EUA Package or an Amendment Thereto	1,292	$97	$125,324
Compliance Officer; Manufacturers of an Unapproved EUA Product	504	$97	$48,888
State and Local Public Health Officials, Medical Health Services Manager; Unapproved EUA Product	2	$140	$280
State and Local Public Health Officials Medical Services Manager, Request for Emergency Dispensing Order	2	$140	$280
State and Local Public Health Officials Medical Services Manager, Request for Expiration Date Extension	20	$140	$2,800
TOTAL			$801,767

RECORDKEEPING: Respondent Labor Category	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
EUA Holders of an Unapproved EUA Product Performing Record Keeping Required Under Conditions of Authorization for Unapproved EUA Product	35,203	$97	$3,414,691

[1] May 2020 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics wage is doubled to include benefits and overhead (https://www.bls.gov/oes/current/naics4_325400.htm).

RECORDKEEPING: Respondent Labor Category	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
State and Local Public Health Authorities Performing Record Keeping Required Under Conditions of Authorization for Unapproved EUA Product	3	$140	$420
TOTAL:			$3,415,111

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We assume 183 full time equivalents (FTEs) (CDRH: 136 FTEs, CBER: 25 FTEs, CDER: 22 FTEs) are allocated to review information submitted in support of an EUA. For CDRH, assuming a cost of $276,400 per one FTE (salary plus overhead, full-time 40 hour work weeks), the estimated annual Federal Government cost is $37,590,400. For CBER and CDER, assuming a cost of $335,053 per one FTE (salary plus overhead, full-time 40 hour week weeks), the estimated annual Federal Government cost is $15,747,491. Cumulatively, this results in expenditures of up to $69,085,382. However we believe most of these review activities are offset by user fees that support marketing application submissions for the same product categories. We therefore assume 5% of this figure, **$3,454,269**, most accurately reflects costs incurred by the FDA as a result of the information collection.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall decrease of 7,087 hours and a corresponding decrease of 302,456 responses. We have decreased our estimated burden to reflect a decrease in related submissions over the past 3 years

16. Plans for Tabulation and Publication and Project Time Schedule

Information collected under this requirement is not planned to be published.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Consistent with established practice, once a draft guidance document is finalized, FDA will publish a Federal Register notice announcing OMB approval of the associated information collection and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on each guidance document cover page and include a link to https://www.reginfo.gov/public/ to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.