UNITED STATES FOOD & DRUG ADMINISTRATION

Emergency Use Authorization of Medical Products and Related Authorities

OMB Control Number 0910-0595

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.

We have developed the guidance document, *"Emergency Use Authorization of Medical Products and Related Authorities"* (January 2017), to assist respondents in understanding the applicable statutory requirements; to provide instruction on submission procedures when requesting an Emergency Use Authorization (EUA) or when making a substantive amendment to an EUA that has previously been issued; to discuss the conditions of authorization; to explain limitations; and to communicate the agency's current thinking on this topic. The guidance document also discusses: (1) submission of requests by stakeholders for a waiver of Current Good Manufacturing Practice (CGMP) requirements for eligible and approved medical countermeasures (MCMs) based on actual or anticipated emergency response activities; (2) submission of requests by manufacturers for a waiver of Risk Evaluation and Mitigation Strategy requirements (REMS) for eligible, FDA-approved MCMs; (3) submission of requests by public health stakeholders to allow emergency dispensing of eligible, FDA-approved MCMs; and (4) submission of requests by stakeholders to extend the expiration date of eligible, approved MCMs not tested within the federal Shelf-Life Extension Program (SLEP).

We are revising the information collection to account for third-party disclosure burden associated with the distribution of EUA information and required statements included in advertising, promotional materials, and fact sheets. In response to an increase in EUAs over the past 3 year period, we have reorganized the information collection to better reflect burden attendant to the distinct collection activities. While we provide what we believe is the average burden across all respondent categories, we have reorganized the information collection activities 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 templates:

Diagnostic Templates (Molecular and Antigen)

- Molecular Diagnostic EUA Cover Sheet Template (October 6, 2021)
- Molecular Diagnostic Template (October 6, 2021)
- Molecular Diagnostic Home Specimen Collection Template (October 6, 2021)
- Antigen Diagnostic Template (October 6, 2021)
- Molecular and Antigen Home Use Test Template (November 9, 2021)
- Supplemental Template for Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing (October 25, 2021)

Serology/Antibody Templates

- Serology Template (October 6, 2021)
- Template for Serology Tests that Detect or Correlate to Neutralizing Antibodies (October 6, 2021)

These templates are part of the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)*, which also includes additional policies specific to this public health emergency. 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 we plan to update them as appropriate as we learn more about the

COVID-19 disease and gain experience with the EUA process for the various types of COVID-19 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 FDA encourages developers to discuss any alternative technological approaches to validating their test with the FDA through CDRH-EUA-Templates@fda.hhs.gov. Members of the public can submit questions about the templates to CDRH-EUA-Templates@fda.hhs.gov, or they can submit comments regarding the templates to the public docket established for the guidance *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)*. Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to CDRH-EUA-Templates@fda.hhs.gov.

We are therefore requesting 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 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 March 3, 2022 (87 FR 12175). Two comments were received. One comment communicated that the information collection has proven useful in expediting the availability of vaccines during the pandemic, and also suggested potential future modifications to the submission of information. The second comment did not respond to the information collection topics solicited in our 60-day notice. Neither comment suggested we revise our burden estimates.

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).

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.

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

No burden was attributed to reporting or recordkeeping for unapproved uses of approved products because, as approved products, they already are subject to approved collections of information: adverse experience reporting for biological products is approved under OMB control number 0910-0308; adverse drug experience reporting is approved under OMB control number 0910-0230; adverse device experience reporting is approved under OMB control number 0910-0471 and 0910-0437; investigational new drug (IND) application regulations are approved under OMB control number 0910-0014; investigational device exemption reporting is approved under OMB control number 0910-0078. In addition, because the procedures for requesting waivers of CGMPs and REMS under section 564A of the FD&C Act are already described elsewhere in FDA regulation and guidance, we do not calculate additional burden for these activities. Waivers for CGMPs for drug and biological products are approved under OMB control number 0910-0139 and for finished devices are approved under OMB control number 0910-0073. Requests for waivers of REMS are approved under OMB control number 0910-0001

for drug products, OMB control number 0910-0338 for biological products, and, for IDEs, OMB control numbers 0910-0078 and 0910-0471.

Section 564(B) of the FD&C Act allows federal, state and local government entities, or persons acting on behalf of a government entity, to pre-position or stockpile MCMs, regardless of the product's regulatory status, in anticipation of FDA approval or clearance, authorization of an investigational use, or the issuance of an EUA, to enable these stakeholders to prepare for potential rapid deployment during an actual CBRN emergency without violating the FD&C Act. Such stockpiling activity is at the discretion of stakeholders, therefore we do not calculate any additional reporting burden to stakeholders for such activities.

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 a substantive amendment to an existing EUA	2724	2	5448	45	245,160
Pre-EUA submissions or amendments	2001	1	2001	34	68,034
Submitting information required under conditions of authorization	36	3	108	8	864
State and local public health authority submissions required under conditions of authorization for unapproved EUA product	1	1	1	2	2
State and local public health authority requests for Emergency Dispensing Order	1	1	1	2	2
State and local public health authority requests for expiration date extension	1	1	1	20	20
Total			7560		314,082

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

EUA Requestor Submitting a Request for EUA or EUA Holder Submitting a Request for a Substantive Amendment to an Existing EUA:

Based on the first year of issuance of EUAs during the declared COVID-19 public health emergency (February 4, 2020 through February 4, 2021), which included several declarations justifying EUA submissions for various product types, we use an upper bound estimate of 5,448 requests annually for FDA to issue an EUA or to amend a previously issued EUA. In some cases, manufacturers directly submit EUA requests. Often a federal government entity (e.g., CDC, DoD) requests that FDA issue an EUA. Variables we considered in estimating burden include whether a request is associated with a novel therapeutic, whether a request is an "original" EUA, or whether a submission is an amendment. Based on recommendations in the guidance, we assume an average reporting burden of 45 hours per EUA request.

Pre-EUA requestor submitting a pre-EUA Package or an Amendment Thereto:

Based on the number of pre-EUA submissions received from February 4, 2020 through February 4, 2021 during the COVID-19 public health emergency, we estimate 2,001 pre-EUA submissions will be filed annually. As with EUA submissions, a federal government entity (e.g., CDC, DoD) often files pre-EUA submissions, and there are varying degrees to which manufacturer respondents inform these requests. Also, as with EUA submissions, there is significant variability in estimates for annual reporting burdens based on the type of product (e.g., novel therapeutic compared to an approved product) and the type of submission (e.g., original pre-EUA submission compared to an amendment to a pre-EUA package). Based on the recommendations in the guidance, we assume an average reporting burden of 34 hours per request.

EUA Holders (e.g., Manufacturers) of an Unapproved EUA Product Submitting Information Required under Conditions of Authorization:

Section 564(e) of the Act prescribes certain conditions of authorization that are mandatory for manufacturers of an unapproved product, to the extent that such conditions are practicable. These include, among other things, requirements for information dissemination to health care providers and potential product recipients and adverse event reporting. We estimate FDA will issue 108 EUAs for unapproved products annually and 108 manufacturers will report under the conditions of authorization of an EUA. We assume the reporting will require 8 hours per response.

State and local Public Health Authorities Submitting Information Required under Conditions of Authorization for Unapproved EUA Product:

If unapproved products needed to be used under an EUA, it is likely that State and local public health officials would be responsible for the administration of EUA products and may need to report to FDA under the conditions of an authorization. We estimate that 1 jurisdiction each year would be involved in administering 1 EUA for unapproved products.

State and local Public Health Authorities Request for Emergency Dispensing Orders:

A State or local Public Health Authority may make a request for an emergency dispensing order. We estimate that 1 jurisdiction each year would request an emergency dispensing order.

State and local Public Health Authorities; Request for Expiration Date Extension:

FDA may be contacted by states requesting information on whether the MCMs they stockpile for public health emergencies can receive expiration date extensions. We plan to make available to public health authorities the lot numbers of specific MCMs with expiration date extensions so that subsequent public health authorities can identify MCMs maintained in their stockpiles that have been granted expiration date extensions. We assume 1 jurisdiction each year would request an expiration date extension and that preparing and submitting such a request will require an average of 20 hours.

Table 2.--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	648	2	1,296	25	32,400
State and local Public Health Authorities	1	1	1	3	3
Total			1,297		32,403

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

EUA Holders (e.g., manufacturers) of an unapproved EUA product:

Section 564(e) of the Act sets out certain conditions of authorization that are mandatory for manufacturers of an unapproved product, to the extent that such conditions are practicable. These include, among other things, recordkeeping requirements. FDA estimates that 648 different manufacturers would need to keep 2 records each year under the conditions of authorization for an EUA. We estimate that such recordkeeping will require approximately 25 hours per record. Therefore, FDA estimates that 32,400 hours per year will be required to prepare such records under the conditions of an authorization.

Public Health Authorities; unapproved EUA product:

If an unapproved product is needed to be used under an EUA, it is likely that State and local public health officials would be responsible for the administration of EUA products and would need to report to FDA under the conditions of an authorization. FDA estimates that 1 jurisdiction each year would be involved in administering 1 EUA for an unapproved product. Therefore, FDA estimates that State and local officials will spend approximately 3 hours per year to prepare and submit information under the conditions of an authorization.

Table 3.--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	635	2	1270	5	6350

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

EUA Holder or Authorized Stakeholder Distributing Information Required:

Under EUA, EUA holders and authorized stakeholders generally must distribute information with required statements, including in advertising and promotional materials, and fact sheets. We estimate 635 entities will annually prepare an average of 2 disclosures each for EUA products. We assume these activities require an average of 5 hours for each disclosure, for a total of 1,270 disclosures and 6,350 hours annually.

12b. Annualized Cost Burden Estimate

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	245,160	$79	$19,367,640
Compliance Officer; Request FDA Review of a Pre-EUA Package or an Amendment Thereto	2,001	$79	$158,079
Compliance Officer; Manufacturers of an Unapproved EUA Product	864	$79	$68,256
State and Local Public Health Officials, Medical Health Services Manager; Unapproved EUA Product	2	$114	$228
State and Local Public Health Officials Medical Services Manager, Request for Emergency Dispensing Order	2	114	$228
State and Local Public Health Officials Medical Services Manager, Request for Expiration Date Extension	20	$114	$2,280
TOTAL			$19,596,711

We assume an hourly wage rate of $79.00 (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 $114.00 (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.

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	32,400	$79	$2,559,600
State and Local Public Health Authorities Performing Record Keeping Required Under Conditions of Authorization for Unapproved EUA Product	3	$114	$342
TOTAL:			$2,559,942

Assuming an average of $79.00 per hour for private sector employees and an average of $114.00 per hour for state and local employees to comply with the recordkeeping for an unapproved EUA product, the total annual burden cost to comply with the recordkeeping information collection requirements outlined in this document would be approximately $2,559,942. Similarly, for the

[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).

third-party disclosures, we estimate 635 entities will cumulatively expend 6,350 hours annually disseminating EUA required information. We assume a mean hourly wage of $79, and calculate an annual cost burden of $501,650.

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 $263,326 per one FTE (salary plus overhead, full-time 40 hour work weeks), the estimated annual Federal Government cost is $35,812,366. For CBER and CDER, assuming a cost of $321,053 per one FTE (salary plus overhead, full-time 40 hour week weeks), the estimated annual Federal Government cost is $15,089,491. Cumulatively, this results in expenditures of up to $50,901,857. 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, **$2,545,092.85**, most accurately reflects costs incurred by the FDA as a result of the information collection.

15. Explanation for Program Changes or Adjustments

We have revised the information collection to include templates developed to help facilitate the preparation, submission, and authorization of an EUA request. We have also accounted for burden that may be associated with the dissemination of required EUA information. As a result of these changes and adjustments, the information collection reflects an increase of 9,766 responses and 348,399 hours annually.

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.