U.S. Food and Drug Administration
Guidance on Emergency Use Authorization of Medical Products and Related Authorities
OMB Control Number 0910-0595
SUPPORTING STATEMENT

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) guidance. The FDA is requesting OMB approval under the Paperwork Reduction Act (5 CFR Part 1320) for a guidance on the Agency's policies applicable to the authorization of the emergency use of certain medical products under 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), as amended or added by the Project BioShield Act of 2004 (Public Law 108-276), the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) (Pub. L. 113-5), 21st Century Cures Act (Pub. L. 114-255), and Public Law 115-92 (2017). The provisions include legal authorities 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.

In addition to incorporating the authorities under section 564 of the FD&C Act (previously approved under OMB Control Number 0910-0595), this guidance describes four collections of information added to the FD&C Act by PAHPRA (section 564A): (1) submission of requests by stakeholders for a waiver of current good manufacturing practices (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 (REMS) requirements for eligible and 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).

For the authorities under section 564 of the FD&C Act (previously approved under OMB Control Number 0910-0595), the guidance describes the six collections of information previously approved: (1) The submission of a request by a manufacturer for FDA to issue an Emergency Use Authorization (EUA) or a substantive amendment to an EUA that has previously been issued, assuming the requisite declaration under section 564 of the FD&C Act has been made and criteria for issuance have been met; (2) the submission of a request by a manufacturer 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) the submission of reports by a manufacturer

of an unapproved EUA product; (4) the submission of reports by State and local public health officials administering an unapproved EUA product; (5) recordkeeping by a manufacturer of an unapproved EUA product; and (6) recordkeeping by State and local public health officials administering an unapproved EUA product.

No burden was attributed to reporting and recordkeeping by the Federal Government (e.g., related to the administration of EUA products). In addition, 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; 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. Prior to passage of PAHPRA, the reporting and recordkeeping requirements for unapproved uses of approved products under section 564 of the FD&C Act were already included for the 4 activities now authorized under 564A and listed above (i.e., expiration date extensions, CGMP waivers, REMS waivers, and emergency dispensing) FDA made more explicit recommendations for one of these uses of approved products under PAHPRA, expiration date extensions, and thus calculated the burdens associated with those activities.

Because the procedures for making requests for waivers of CGMPs and REMS under the new PAHPRA authorities (section 564A of the FD&C Act) are already described elsewhere in FDA regulation and guidance, FDA has not calculated additional burden for these authorities because such requests are already approved under existing OMB control numbers. 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. Requests for emergency dispensing orders also were previously covered under requests to issue an EUA under OMB 0910-0595. Because the procedures for making requests for expiration dating extensions under section 564A are being spelled out more explicitly in this guidance, FDA is requesting OMB approval for associated reporting and recordkeeping as described in more detail below.

For the authorities under section 564A (previously approved under OMB Control Number 0910-0595), the guidance describes four collections of information previously approved: (1) submission of requests by stakeholders for a waiver of CGMP requirements for eligible and approved 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).

Section 564(B) 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. Previously, FDA issued an EUA or exercised its enforcement discretion to allow stockpiling of MCMs. Such stockpiling activity is at the discretion of stakeholders, therefore FDA is not calculating any additional reporting burden to stakeholders for such activities. While the guidance recommends that to the extent feasible stakeholders maintain records to readily identify their pre-positioned MCMs and track their storage, distribution and ultimate disposition of these MCMs, FDA is not recommending any additional recordkeeping, other than, for approved products that are already part of CGMP requirements, and for unapproved products any recordkeeping that is part of the mechanisms by which the unapproved product might subsequently be approved, e.g., an IND/IDE or EUA. These recordkeeping burdens are already approved under OMB control number 0910-0139 and OMB control number 0910-0073 for CGMPs for finished pharmaceuticals and finished devices and OMB control number 0910-0014 for investigational new drug application (IND) regulations; therefore, FDA is not calculating any additional recordkeeping burden for prepositioning MCMs by stakeholders.

Because this guidance provides recommendations for submitting information to FDA in support of a request for an EUA for use of an unapproved medical product under section 564 of the FD&C Act and for expiration date extensions under section 564A of the FD&C Act, FDA is requesting OMB approval for the following reporting and recordkeeping recommendations:

- Requests for FDA to issue an EUA or a substantive amendment to an existing EUA, assuming the requisite declaration under section 564 of the FD&C Act has been made and criteria for issuance have been met

The guidance provides recommendations for submission of data and information to meet the criteria for issuance of an EUA authorization that are set out in section 564(c) of the Act. Among other things, data supporting an EUA must demonstrate that, based on the totality of the scientific evidence available to the agency, 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; the known and potential benefits of the product outweigh the known and potential risks; and there is no adequate, approved, and available alternative to the product. Although the exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency and the nature of the candidate product, the guidance provides recommendations for 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.

- Requests 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

Recognizing that during an emergency, the time available for the submission and review of an EUA request may be severely limited, the guidance encourages entities with candidate products to submit data and information on a candidate product prior to a determination of emergency (i.e., pre-EUA submissions). The same data recommendations that apply to a Request for Consideration for an EUA also apply to a pre-EUA submission.

- Reporting by a manufacturer of an unapproved EUA product for certain conditions under section 564 of the FD&C Act

Section 564(e) of the Act requires the FDA Commissioner (to the extent practicable given the circumstances of the emergency) to establish certain conditions on the authorized use of an EUA that the Commissioner finds necessary or appropriate to protect the public health. Those conditions include adverse event monitoring and reporting by manufacturers of an unapproved medical product authorized for emergency use. The statute also gives the FDA Commissioner authority to establish other conditions of authorization necessary or appropriate to protect the public health.

- Reporting by State and local public health officials of an unapproved EUA product for certain conditions under section 564 of the FD&C Act

The requirements to perform adverse event monitoring and reporting are mandatory (to the extent practicable given the circumstances of the emergency) under section 564(e) on any person who carries out any activity for an unapproved EUA product. If unapproved products were to be used under an EUA, it is likely that State and local public health officials would be involved in the administration of EUA products. Accordingly, PRA burden is calculated for State and local public health officials who would be required to perform activities related to product administration and information dissemination under the terms of an EUA authorization.

- Reporting by Public Health Authorities for expiration date extensions of approved medical products under section 564A of the FD&C Act

The expiration date extension authority in section 564A applies to any eligible MCM, including eligible MCMs tested through the federal Shelf-Life Extension Program (SLEP). FDA has engaged with federal partners in SLEP since the 1980s; the program is administered by DoD, while FDA tests the stability of certain federally stockpiled drug products to assess, and extend as appropriate, the useful shelf-life of such products. Federal participants in SLEP will continue to submit requests to extend the expiration

date of eligible MCMs using established processes administered by DoD. However, for drug products not tested within the SLEP program, state and local public health stakeholders may need to submit a request for expiration date extensions for stockpiled medical products. Because any such request would be for an approved product, any burden on manufacturers making any such request would be covered by previously approved collections of information. However, FDA anticipates that some requests for expiration date extensions may come from non-federal public health authorities maintaining stockpiles for emergency uses. Therefore, FDA is calculating burden for State and local public health emergency response stakeholders who may submit such requests. FDA is not calculating recordkeeping burden for expiration date extensions because public health stakeholders maintain records with this information for the MCMs they stockpile; maintaining records of expiration dates for stockpiled MCMs is part of recordkeeping systems already created and maintained by states and local public health authorities.

- Recordkeeping by manufacturers of an unapproved EUA product under section 564 of the FD&C Act

Section 564(e) provides that the FDA Commissioner shall establish appropriate conditions with respect to manufacturers' recordkeeping, reporting, and records access, to the extent that such conditions are practicable.

- Recordkeeping by State and local public health officials regarding an unapproved EUA product under section 564 of the FD&C Act

The FDA Commissioner also may, under section 564(e), impose comparable records conditions for manufacturers' on any person (e.g., State and local public health officials) carrying out any activity for which an authorization is issued.

2. Purpose and Use of the Information Collection

The submissions described in the guidance provide the means by which FDA can, among other things, determine whether a candidate product meets the statutory criteria for issuance of an EUA authorization under section 564(c) of the Act. The Agency will use information submitted in compliance with a condition of authorization for the following purposes: to (1) track the distribution and administration of an EUA product; (2) monitor the information being disseminated to health care professionals and other authorized dispensers and potential product recipients or caregivers regarding the known and potential risks and benefits of an EUA product, an individual's option to refuse the product, and the possible consequences of refusal; (3) obtain timely information on adverse reactions to an EUA product; (4) obtain other information pertinent to determining whether the authorization should be revoked because the statutory criteria for issuance are no longer met; (5) determine whether a manufacturer or other person acting under an EUA has complied with the conditions of the authorization; and (6)

prepare pre-EUA packages to be poised for timely issuance should there be a determination of emergency justifying issuance of the EUA.

The submissions described in this guidance also provide the means by which FDA can 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).

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that 95% of the respondents will use electronic means to fulfill the agency's requirement or request.

FDA has developed several guidances for industry to improve the use of information technology in the submission of marketing applications for human drugs and related reports.

Section 745A(b) of the FD&C Act, added by section 1136 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), provides statutory authority to require eCopies after issuance of final guidance (See Pub. L. No: 112-144). FDA's implementing guidance describes how device companies should replace one paper copy of a device application with an eCopy and identify the required format and technical requirements of the eCopy. The eCopy requirement does not require or request any information that is not already submitted to the Agency and/or covered under the existing ICR, and therefore does not change the cost or hour burden.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Agency that has the power, by delegation from the Secretary of Health and Human Services, to issue EUAs for medical products under section 564 of the Act; similarly, FDA is the only Agency that has the authority to issue expiration dating extensions, emergency, mass dispensing orders, and CGMP and REMS waivers for FDA-approved products under section 564A of the Act. FDA would be the only Agency that would collect this information.

5. Impact on Small Businesses or Other Small Entities

Although the majority of drug products are developed by large pharmaceutical companies, medical countermeasures typically are developed by small companies. Generally, the information collection requested under the guidance will apply to small companies. 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, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health, consult with, and expend considerable resources providing technical assistance to, small businesses and other interested companies regarding EUA submissions.

6. Consequences of Collecting the Information Less Frequently

Less frequent collection of the information described above would significantly limit the FDA Commissioner's ability to determine whether the statutory criteria for issuance of an authorization of an unapproved product or unapproved use of an approved product were met and to ensure compliance with the conditions of the authorization. Moreover, the information required by and reported under a condition of authorization is critical to an appropriate public health response should significant adverse events occur once an EUA product is administered widely. It also would provide early warning if a product no longer met the criteria for authorization. Information collected for preparation of pre-EUA packages is critical to the U.S. Government's ability to respond in a timely manner to the relevant medical emergencies. Information collected to extend expiration dates of FDA-approved products stockpiled for public health emergencies is critical to meeting the needs of Federal, State and local governments to maintain critical supplies of medical countermeasures for the U.S. population in the event of a CBRN emergency.

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

The recordkeeping and reporting requirements set out in the guidance are consistent with the guidelines in 5 CFR 1320.5(d)(2), including the frequency of reporting. However, the Agency recognizes that the FDA Commissioner may, due to the risk-benefit profile of a particular EUA product, require more frequent reporting as a condition of authorization.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of April 4, 2019 (84 FR 13299). Although one comment was received, it was not responsive to the four collection of information topics solicited.

9. Explanation of Any Payment or Gift to Respondents

FDA did not provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

This ICR is not collecting personally identifiable information (PII) or other data of a personal nature. It collects information from manufacturers and public health authorities applicable to the authorization of the emergency use of certain medical products during a declared emergency. Respondents submit information as recommended in Agency guidance, including a description of the medical product and the intended use, reports after administration of such a product, and requests for extension of the expiration date of eligible products.

Confidentiality of the information submitted under this guidance is protected under 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under section 310(j) of the Act.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA determined that personally identifiable information (PII) is not collected, and the Privacy Act does not apply to this collection

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The total annual burden estimate for this information collection is 4435 hours. The estimated reporting burden for this collection is 3565 hours and the estimated recordkeeping burden is 870 hours.

12 a. Annualized Hour Burden Estimate

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

[1]

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

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (Hours)	Total Hours
Requests to Issue an EUA or a Substantive Amendment to an Existing EUA	12	2.39	29	45	1,305
FDA Review of a Pre-EUA Package or an Amendment Thereto	32	1.79	57	34	1,938
Manufacturers of an Unapproved EUA Product	12	5.8	70	2	140
Public Health Authorities; Unapproved EUA Product	30	3	90	2	180
Public Health Authorities; Request for Expiration Date Extension	1	1	1	2	2
Total					3,565

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

The reporting burden is based on the following:

- Requests to Issue an EUA or a Substantive Amendment to an Existing EUA

Based on the previous three years' experience, which has included four determinations of actual or potential emergencies involving a CBRN agent and declarations justifying EUA submissions, FDA anticipates continued occurrences of such determinations and declarations. Therefore, FDA estimates that six requests for FDA to issue an EUA or to amend a previously issued EUA will be filed annually. In some cases, manufacturers directly submit EUA requests. Often a federal government entity (e.g., CDC, DOD) requests that FDA issue an EUA. In many of these cases, manufacturer respondents inform these requests, which are the activities that form the basis of the estimated reporting burdens. However, in some cases such as with antimicrobial products for which there are multiple generic manufacturers, the federal government is the sole respondent; manufacturers do not inform these requests or submissions. FDA estimates minimal burden when the federal government performs the relevant activities. In addition to variability based on whether there is an active manufacturer respondent, other factors also inject significant variability in estimates for annual reporting burdens. A second factor is the type of product. For example, FDA estimates greater burden for novel therapeutics than for certain unapproved uses of approved products. A third significant factor that injects variability is the type of submission. For example, FDA estimates greater burden for an "original" EUA than for amendments to them, and FDA estimates minimal burden to issue an EUA when there is a previously reviewed pre-EUA package or investigational application. For purposes of estimating the reporting burden, FDA has calculated the anticipated burden on manufacturers based on the anticipated types of responses (i.e., estimated manufacturer input), types of product, and types of submission that comprise the described reporting activities. Based on the recommendations in the guidance, FDA estimates the average reporting burden to be 45 hours per Request. This estimate anticipates as few as no hours (i.e., when there is no manufacturer input) to as many as 70 hours (i.e., for novel therapeutic products). Therefore, FDA estimates that a total of approximately 1,305 hours per year will be required to prepare and submit Requests for FDA to Issue an EUA or a Substantive Amendment to an Existing EUA.

- Requests to Review a Pre-EUA Submission or Substantive Amendment Thereto

Based on the number of pre-EUA submissions that the Agency received in the past three years, FDA estimates that 32 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, FDA estimates the average reporting burden to be 34

hours per request. As with requests for an EUA, this estimate anticipates as few as no hours (i.e., when there is no manufacturer input) to as many as 80 hours (i.e., for novel therapeutic products). Therefore, FDA estimates that a total of approximately 1,938 hours per year will be required to prepare and submit requests for FDA to review a pre-EUA submission or a substantive amendment to an existing pre-EUA package.

- Manufacturers of an Unapproved EUA Product; conditions of authorizations

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, requirements for information dissemination to health care providers and potential product recipients and adverse event reporting. FDA estimates that it will issue 12 EUAs for unapproved products annually and that 2 manufacturers would need to report under the conditions of an EUA. The Agency estimates that such reporting will require approximately two hours per response. Therefore, FDA estimates that 140 hours per year will be required to prepare and submit manufacturers' reports to the Agency under the conditions of an authorization.

- Public health authority, unapproved EUA product; conditions of authorizations

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 would need to report to FDA under the conditions of an authorization. The Agency estimates that 30 jurisdictions each year would be involved in administering three EUAs for unapproved products. Therefore, the FDA estimates that State and local officials will spend approximately 180 hours per year to prepare and submit information under the conditions of an authorization.

- Public health authorities; requests for expiration date extension

FDA has been contacted by several states requesting information on whether the MCMs they stockpile for public health emergencies can receive expiration date extensions. These burden estimates are based on discussions with these stakeholders and their indications of anticipated needs. FDA plans 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.

Table 2.-Estimated Annual Recordkeeping Burden[1]

Type of Respondent	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Manufacturers of an Unapproved EUA Product	12	2	24	25	600

Public Health Authorities; Unapproved EUA Product	30	3	90	3	270
Total					870

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

The recordkeeping burden is based on the following:

- 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 five different manufacturers would need to keep such records for 2 products each year under the conditions of an EUA. The Agency estimates that such recordkeeping will require approximately 25 hours per record. Therefore, FDA estimates that 600 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 30 jurisdictions each year would be involved in administering three EUAs for unapproved products. Therefore, FDA estimates that State and local officials will spend approximately 270 hours per year to prepare and submit information under the conditions of an authorization.

12b. Annualized Cost Burden Estimate

We estimate an average industry wage rate of $81.00 per hour, including overhead and benefits, for employees in the private sector preparing and submitting the information collection requirements outlined in this document. This estimate is based on the U.S. Bureau of Labor and Statistics (BLS) North American Industry Classification System (NAICS) occupational category for a compliance officer in Pharmaceutical and Medicine Manufacturing. For employees of state and local governments, we estimate an average hourly wage rate of $92.00 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. Assuming an average of $81.00 per hour for private sector employees and an average of $92 per hour for state and local employees to comply with the recommendations and conditions of authorization,

the total annual burden cost to comply with the information collection requirements outlined in this document would be approximately $290,767.

Type of Respondent	Total 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	1305	$81	$ 105,705
Compliance Officer; FDA Review of a Pre-EUA Package or an Amendment Thereto	1938	$81	$156,978
Compliance Officer; Manufacturers of an Unapproved EUA Product	140	$81	$11,340
State and Local Public Health Officials, Medical Health Services Manager; Unapproved EUA Product	180	$92	$16,560
State and Local Public Health Officials Medical Services Manager, Request for Expiration Date Extension	2	$92	$184
Total			$ 290,767

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

FDA estimates it would need approximately 35 full time equivalents (FTEs) to review the information submitted under the EUA guidance. If each FTE equals approximately $170,000, the annualized cost burden to FDA would be $ 5.95 million.

15. Explanation for Program Changes or Adjustments

The estimated annual hourly burden, formerly estimated as 1,622 hours, has increased by 2,813 hours to a total estimated annual hourly burden of 4,435 hours. This program adjustment/increase in total annual burden is a result of calculations based on the numbers of submissions over the past three years. FDA anticipates that there will be a similar number of pre-EUA, EUA, and expiration date extension request submissions in future 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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.