UNITED STATES FOOD & DRUG ADMINISTRATION

Adverse Event and Products Experience Reports;
Electronic Submissions

OMB Control No. 0910-0645

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) laws and regulations governing adverse event reports and product experience reports for FDA-regulated products. The Federal Food, Drug, and Cosmetic Act (FD&C Act, the act) (21 U.S.C. 353b, 355, 360i, 360l, 379aa, and 393) and the Public Health Service Act (42 U.S.C. 262) authorize FDA to collect adverse event reports and product experience reports from regulated industry. These reporting and recordkeeping requirements are found in FDA regulations, discussed in agency guidance, and included in agency forms. To facilitate both consumer and industry reporting of adverse events and experiences with FDA-regulated products, we developed the "*MedWatch*" program. The MedWatch program allows anyone to submit reports to FDA on adverse events, including injuries and/or deaths, as well as other product experiences associated with the products we regulate. The MedWatch program provides for both paper-based and electronic reporting. Paper-based MedWatch reporting is approved under OMB control number 0910-0291. This request supports electronic adverse event reporting to FDA, including electronic MedWatch reporting and other electronic adverse event reporting.

The FDA Safety Reporting Portal (the SRP) and the Electronic Submission Gateway (ESG) are the agency's electronic systems for collecting, submitting, and processing adverse event reports, product problem reports, and other safety information for FDA-regulated products. To ensure the safety and identify any risks, harms, or other dangers to health for all FDA-regulated human and animal products, we need to be informed whenever an adverse event, product quality problem, or product use error occurs. This risk identification process is the first necessary step that allows the us to gather the information necessary to be able to evaluate the risk associated with the product and take whatever action is necessary to mitigate or eliminate the public's exposure to the risk.

Some adverse event reports are required to be submitted to FDA (mandatory reporting) and some adverse event reports are submitted voluntarily (voluntary reporting). Requirements regarding mandatory reporting of adverse events or product problems have been codified in 21 CFR parts 310, 314, 514, 600, 803 and 1271, specifically §§ 310.305, 314.80, 314.98, 314.540, 329.100, 514.80, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56 and 1271.350(a) (21 CFR 310.305, 314.80, 314.98, 314.540, 329.100, 514.80, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56 and 1271.350(a)). While adverse event reports submitted to FDA in paper format using FDA Forms FDA 3500, 3500A, 1932, and 1932a, are approved under OMB control numbers 0910-0284 and 0910-0291, this information collection request concerns adverse event reports filed electronically via the SRP and the ESG, and currently approved under OMB control number 0910-0645. Initital data input is captured via electronic Form FDA 3800 and systematically directed to the appropriate agency component(s).

We therefore request extension of OMB approval for the information collection provisions covered in the applicable regulations, discussed in this supporting statement, and as outlined below.

The FDA Safety Reporting Portal Rational Questionnaires:

A. Reportable Food Registry Reports

The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–085) (FDAAA) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by creating section 417 (21 U.S.C. 350f), Reportable Food Registry (RFR or the Registry). Section 417 of the FD&C Act defines "*reportable food*" as an article of food (other than infant formula) for which there is a "*reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals*." (See section 417(a)(2) of the FD&C Act). The Secretary of Health and Human Services (the Secretary) has delegated to the FDA Commissioner the responsibility for administering the FD&C Act, including section 417. The purpose of the RFR is to enable the Agency to track patterns of adulteration in food to support its efforts to target limited inspection resources to protect the public health. We designed the RFR report rational questionnaire to enable FDA to quickly identify, track, and remove from commerce an article of food (other than infant formula and dietary supplements) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. Our Center for Food Safety and Applied Nutrition (CFSAN) uses the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses. The data elements for RFR reports remain unchanged in this request for extension of OMB approval.

B. Reports Concerning Experience With Approved New Animal Drugs

Section 512(l) of the FD&C Act (21 U.S.C. 360b(l)) and § 514.80(b) of FDA's regulations (21 CFR 514.80) require applicants of approved new animal drug applications (NADAs) and approved abbreviated new animal drug applications (ANADAs) to report adverse drug experiences and product/manufacturing defects to the Center for Veterinary Medicine (CVM). This continuous monitoring of approved NADAs and ANADAs affords the primary means by which FDA obtains information regarding potential problems with the safety and efficacy of marketed approved new animal drugs as well as potential product/manufacturing problems. Postapproval marketing surveillance is important because data previously submitted to FDA may no longer be adequate, as animal drug effects can change over time and less apparent effects may take years to manifest.

If an applicant must report adverse drug experiences and product/manufacturing defects and chooses to do so using the Agency's paper forms, the applicant is required to use Form FDA 1932, "*Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report*." Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301, "*Transmittal of Periodic Reports and Promotional Material for New Animal Drugs*" (see § 514.80(d)). Form FDA 1932a, "*Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report*" allows for voluntary reporting of adverse drug experiences or product/manufacturing defects by veterinarians and the general public. Collection of information using existing paper Forms FDA 2301, 1932, and 1932a is approved under OMB control number 0910–0284.

Alternatively, respondents may choose to report adverse drug experiences and product/manufacturing defects electronically. The electronic submission data elements to report adverse drug experiences and product/manufacturing defects electronically remain unchanged in this request for extension of OMB approval.

C. Animal Food Adverse Event and Product Problem Reports

Section 1002(b) of FDAAA directed the Secretary to establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. As part of the effort to fulfill that directive, the Secretary tasked FDA with developing the instrument that would allow consumers to report voluntarily adverse events associated with pet food. We developed the Pet Food Early Warning System rational questionnaire as a user-friendly data collection tool, to make it easy for the public to report a safety problem with pet food. Subsequently, we developed a questionnaire for collecting voluntary adverse event reports associated with livestock food from interested parties such as livestock owners, managers, veterinary staff or other professionals, and concerned citizens. Information collected in these voluntary adverse event reports contribute to CVM's ability to identify adulteration of the livestock food supply and outbreaks of illness associated with livestock food. The Pet Food Early Warning System and the Livestock Food Reports are designed to identify adulteration of the animal food supply and outbreaks of illness associated with animal food to enable us to quickly identify, track, and remove from commerce such articles of food. We use the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses. The electronic submission data elements to report adverse events associated with animal food remain unchanged in this request for extension of OMB approval.

D. Voluntary Tobacco Product Adverse Event and Product Problem Reports

FDA has broad legal authority under the FD&C Act to protect the public health, including protecting Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others. The Family Smoking Prevention and Tobacco Control Act of 2009 (Pub. L. 111-31) (Tobacco Control Act) amended the FD&C Act by creating a new section 909 (21 U.S.C. 387i, Records and Reports on Tobacco Products). Section 909(a) of the FD&C Act (21 U.S.C. 387i(a)) authorizes FDA to establish regulations with respect to mandatory adverse event reports associated with the use of a tobacco product. FDA collects voluntary adverse event reports associated with the use of tobacco products from interested parties such as health care providers, researchers, consumers, and other users of tobacco products. Information collected in voluntary adverse event reports contributes to the Center for Tobacco Products' (CTP's) ability to be informed of, and assess the real consequences of, tobacco product use.

The need for this collection of information derives from our responsibility to obtain current, timely, and policy-relevant information to carry out our statutory functions. The Commissioner of Food and Drugs is authorized to undertake this collection as specified in section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)). CTP has been receiving adverse event and product problem reports through the Safety Reporting Portal since January 2014, when the Safety Reporting Portal for tobacco products first became available to the public. CTP also receives adverse event and product problem reports via paper forms, as approved under OMB Control number 0910-0291.

CTP has two voluntary rational questionnaires on the Safety Reporting Portal. The first is utilized by consumers and concerned citizens, manufacturers, and healthcare professionals to report tobacco product adverse event or product problems. A second rational questionnaire is used by tobacco product investigators in clinical trials with investigational tobacco products. In addition to the information collected by the first rational questionnaire for tobacco products, the second rational questionnaire collects identifying information specific to the clinical trial or investigational product such as clinical protocol numbers or other identifying features to pinpoint under which test or protocol the adverse event occurred.

Both CTP voluntary rational questionnaires capture tobacco-specific adverse event and product problem information from reporting entities such as health care providers, researchers, consumers, and other users of tobacco products. To carry out its responsibilities, FDA needs to be informed when an adverse event, product problem, or error with use is suspected or identified. FDA uses tobacco-specific adverse event and product problem information to assess and evaluate the risk associated with the product and to take whatever action is necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions. The burden for CTP remains unchanged.

E. Dietary Supplement Adverse Event Reports

The Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA) (Pub. L. 109–462, 120 Stat. 3469) amended the FD&C Act with respect to serious adverse event reporting and recordkeeping for dietary supplements and nonprescription drugs marketed without an approved application.

Section 761(b)(1) of the FD&C Act (21 U.S.C. 379aa–1(b)(1)) requires the manufacturer, packer, or distributor whose name (under section 403(e)(1) of the FD&C Act (21 U.S.C. 343(e)(1)) appears on the label of a dietary supplement marketed in the United States to submit to FDA all serious adverse event reports associated with the use of a dietary supplement, accompanied by a copy of the product label. The manufacturer, packer, or distributor of a dietary supplement is required by the DSNDCPA to use the MedWatch form (Form FDA 3500A) when submitting a serious adverse event report to FDA. In addition, under section 761(c)(2) of the FD&C Act, the submitter of the serious adverse event report (referred to in the statute as the "*responsible person*") is required to submit to FDA a followup report of any related new medical information the responsible person receives within 1 year of the initial report.

As required by section 3(d)(3) of the DSNDCPA, we issued guidance to describe the minimum data elements for serious adverse event reports for dietary supplements. The guidance document entitled "*Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act*," discusses how, when, and where to submit serious adverse event reports for dietary supplements and followup reports. The guidance also provides FDA's recommendation on records maintenance and access for serious and non-serious adverse event reports and related documents. The reporting and recordkeeping requirements of the FD&C Act for dietary supplement adverse event reports and the recommendations of the guidance document were first approved in 2009 under OMB control number 0910-0635. The guidance is now currently approved under OMB Control No. 0910-0291.

Reporting of serious adverse events for dietary supplements to FDA serves as an early warning sign of potential public health issues associated with such products. Without notification of all serious adverse events associated with dietary supplements, FDA would be unable to investigate and follow up promptly, which in turn could cause delays in alerting the public when safety problems are found. In addition, the information received provides a reliable mechanism to track patterns of adulteration in food that supports efforts by FDA to target limited inspection resources to protect the public health. FDA uses the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses.

Paper mandatory dietary supplement adverse event reports are submitted to FDA on the MedWatch form, Form FDA 3500A, and paper voluntary reports are submitted on Form FDA 3500. Forms FDA 3500 and 3500A are available as fillable pdf forms. Dietary supplement adverse event reports may be electronically submitted to the agency via the SRP. This method of submission is voluntary. A manufacturer, packer, or distributor of a dietary supplement who is unable to or chooses not to submit reports using the electronic system will still be able to provide their information by paper MedWatch form, Form FDA 3500A (by mail or Fax). There is no change to the mandatory information previously required on the MedWatch form. CFSAN is making available the option to submit the same information via electronic means.

F. Food, Infant Formula, and Cosmetic Adverse Event Reports

We continue to work on proposed new rational questionnaire functionality that will be used for food, infant formula and cosmetic adverse event reports over the SRP. Currently, voluntary adverse event reports for such products are submitted on Form FDA 3500, which is available as a fillable pdf form. We have now developed rational questionnaires by which these reports may be electronically submitted to us via the SRP. In addition, MedWatch forms, although recently updated with field labels and descriptions to better clarify for reporters the range of reportable products, do not specifically include questions relevant for the analysis of adverse events related to food, infant formula, and cosmetics. The proposed food, infant formula, and cosmetics rational questionnaire functionality will operate in a manner similar to the dietary supplement rational questionnaire and will include specific questions relevant for the analysis of adverse events related to food, infant formula, and cosmetics. The electronic submission data elements to report adverse events associated with food, infant formula, and cosmetics products remain unchanged in this request for extension of OMB approval.

2. Purpose and Use of the Information Collection

FDA is charged with the responsibility for ensuring that the products it regulates are safe and effective. To fulfill our public health protection responsibilities, we need to be informed whenever an adverse event, product problem, or product use error occurs. Information collected in electronic adverse event reports serves as an early warning sign of potential public health issues associated with FDA-regulated products. We use the information to assess potential public health issues, evaluate the risk, if any, associated with the product, and take whatever action is necessary to reduce, mitigate, or eliminate the public's exposure to the risk. In addition, the information received provides a reliable mechanism to track patterns of adulteration in FDA-regulated products and supports efforts by FDA to target limited inspection resources to protect the public health. Without notification of all adverse events associated with products it regulates, we are unable to investigate

and follow up promptly, which in turn could cause delays in alerting the public when safety problems are found. The need for this collection of information derives from our objective to obtain current, timely, and policy-relevant information to carry out our statutory functions.

Description of Respondents: The respondents to this collection of information include all persons submitting mandatory or voluntary adverse event reports electronically to FDA via the ESG or the SRP regarding FDA-regulated products. Respondents include, unless otherwise exempt, individuals and households, the private sector (including for-profit businesses, not-for-profit institutions and farms), state local or tribal governments, as well as the Federal government.

3. Use of Improved Information Technology and Burden Reduction

This information collection request seeks OMB approval of electronic submission of all FDA adverse event reports and other safety information submitted via the SRP and ESG. Thus, one hundred percent (100%) of the respondents will use electronic means to submit the required information.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Mandatory adverse event reporting of FDA-regulated products is required by statute and mandated by Congress. In the event that we receive a report on a product that is not under our jurisdiction, the report will be forwarded to the appropriate Federal agency. For example, adverse event reports submitted for biologic products used for animals will be forwarded to the U.S. Department of Agriculture.

5. Impact on Small Businesses or Other Small Entities

We estimate that fifty percent (50%) of respondents are small businesses. For mandatory reporters, the same information is required from large and small firms by statute or regulation and is the minimal amount needed. There is no special burden placed on small businesses by these information collection provisions. We note that the SRP is available to all users through the internet, without requiring the use of special software. However, FDA aids small businesses in complying with its requirements through the Agency's Regional Small Business Representatives and through the scientific and administrative staffs within the Agency. FDA has provided a Small Business Guide on the Agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. Original adverse event and safety reports are submitted only once and therefore cannot be collected less frequently.

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

Due to the nature of adverse event reporting, this information collection involves more than quarterly submission of information and written responses in less than 30 days. The specific reporting timeframes required by statute or regulation are provided in Table 1 for each report.

Table 1.—Required Timeframes for Submitting Reports	
Name of Report:	Reporting Timeframe:
Reportable Food Registry Reports	Under section 417(d)(1) of the FD&C Act, a responsible party is required to submit a reportable food registry report to FDA as soon as practicable, but in no case later than 24 hours after determining that the food is an "article of food (other than infant formula or dietary supplements) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals." (See section 417(a)(2))
Reports Concerning Experience With Approved New Animal Drugs	Pursuant to 21 CFR 514.80(b)(1), the applicant is required to submit product and manufacturing defects that may result in serious adverse drug events are to be reported within 3 working days of first becoming aware that a defect may exist. Pursuant to 21 CFR 514.80(b)(2)(i)-(ii), the applicant is required to submit initial and follow-up reports within 15 working days. Pursuant to 21 CFR 514.80(b)(3), the non-applicant is required to report adverse drug experiences to the applicant within 3 working days of first receiving the information or if reported to FDA within 15 working days.
Animal Food Adverse Event and Product Problem Reports	These are voluntary reports. There is no required timeframe for submission.
Voluntary Tobacco Product Adverse Event and Product Problem Reports and Investigator Reports	These are voluntary reports. There is no required timeframe for submission.
Dietary Supplement Adverse Event Reports	Mandatory reports - Serious adverse event reports received through the address or phone number on the label of a dietary supplement, as well as all follow-up reports of new medical information received by the responsible person within one year after the initial report, must be submitted to FDA no later than 15 business days after the report is received by the responsible person. Section 761(c)(1)-(2) of the FD&C Act (21 U.S.C. 379aa-1(c)(1)-(2)). Voluntary reports - There is no required timeframe for submission of a voluntary report.
Food, Infant Formula and Cosmetic Adverse Event Reports	These are voluntary reports. There is no required timeframe for submission.

Short timeframes for reporting are necessary so that FDA is informed as soon as possible of any serious problems with products that it regulates. Delayed or less frequent reporting of some serious adverse events to FDA would lessen the effectiveness of adverse event reporting as an early warning sign of possible safety problems with FDA-regulated products. Without notification of all serious adverse events, FDA would be unable to investigate and follow-up promptly, which in turn could cause delays in alerting the public when safety problems are found.

This collection of information does not involve submission of more than an original and 2 copies, the use of statistical methods, pledges of confidentiality by FDA not supported by authority established in statute or regulation, or require the disclosure of trade secrets or other confidential information.

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

In accordance with 5 CFR 1320.8(d), in the Federal Register of November 30, 2018 (83 FR 61653), we published a 60-day notice requesting public comment on the proposed revision of this information collection. We received two comment messages, each containing one or more comments.

(Comment 1) One comment suggests that the electronic forms are hard to use and not user-friendly and expresses concern that the public not be forced to mail adverse event reports due to the cost.

(Response 1) We continually strive to improve the usability of the rational questionnaires. The rational questionnaire provides reporters, including voluntary reporters, with detailed navigation instructions that include drop-down menus, lists of values, controlled vocabularies, and mouse over help where possible. We develop new rational questionnaires with the assistance of professional organizations and community interest groups and collect feedback during user acceptance testing. To avoid postage costs for paper reporting, voluntary reporters may report adverse events by telephone by calling the FDA toll free at 1-800-FDA-1088.

(Comment 2) Another comment generally supports the information collection.

(Response 2) We appreciate the general support that the comment expresses.

In addition, we received comments that were not responsive to the four collection of information topics set forth in the notice. These comments express views about matters unrelated to the subject matter of the notice and are therefore not addressed in this document.

9. Explanation of Any Payment or Gift to Respondents

No gifts or payments are provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

This ICR collects personally identifiable information (PII). Depending on the type of FDA-regulated product and whether the report is mandatory or voluntary, the rational questionnaires may collect patient identifier, age, sex, date of birth, ethnicity, race, weight, first name, last name, address, telephone number, email address, fax number, and information about the adverse event.

The HIPAA Privacy Rule (the Rule) recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to protected health information to carry out their public health mission. See Disclosures for Public Health Activities, 45 CFR 164.512(b). The Rule also recognizes that public health reports made by covered entities are an important means of identifying threats to the health and safety of the public at large, as well

as individuals. Accordingly, the Rule permits covered entities to disclose protected health information without authorization for specified public health purposes. Covered entities may disclose protected health information to a person subject to FDA jurisdiction, for public health purposes related to the quality, safety or effectiveness of an FDA-regulated product or activity for which that person has responsibility. Examples of purposes or activities for which such disclosures may be made include, but are not limited to:

- Collecting or reporting adverse events (including similar reports regarding food and dietary supplements), product defects or problems (including problems regarding use or labeling), or biological product deviations;
- Tracking FDA-regulated products;
- Enabling product recalls, repairs, replacement or look back (which includes locating and notifying individuals who received recalled or withdrawn products or products that are the subject of look back); and
- Conducting post-marketing surveillance.

The "*person*" subject to the jurisdiction of the FDA does not have to be a specific individual. Rather, it can be an individual or an entity, such as a partnership, corporation, or association.

Release of information submitted to FDA in voluntary adverse experience reports is governed by 21 CFR 20.63(f), which prohibits FDA and a manufacturer in possession of such reports from releasing to the public the names of patients, individual reporters, health care practitioners, hospitals, and any geographic identifiers.

Confidential commercial information is protected from disclosure under FOIA under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of our regulations (21 CFR part 20). To the extent 21 CFR 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

We have also determined that, although PII is collected, the notice and statement provisions of the Privacy Act of 1974 do not apply to the instant ICR. Specifically, we do not use *name* or any other personal identifier to routinely retrieve records from information submitted via Forms FDA 3500 and 1932a, or otherwise in relation to this collection.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature (e.g., those regarding sexual behavior and attitudes, religious beliefs, etc).

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

Table 2 – Estimated Annual Reporting Burden[1]						
Activity	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Voluntary Adverse Event Report via the SRP (Other than RFR Reports)	3800	1,800	1	1,800	0.6 (36 mins.)	1,080
Mandatory Adverse Event Report via the SRP (Other than RFR Reports)	3800	3,360	1	3,360	1	3,360
Mandatory Adverse Event Report via the ESG (Gateway-to-Gateway transmission)	3800	3,007,000	1	3,007,000	0.6 (36 mins.)	1,804,200
Mandatory and Voluntary RFR Reports via the SRP	3800	1,260	1	1,260	0.6 (36 mins.)	756
TOTAL				3,013,420		1,809,396

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

Our estimate of the number of respondents and the total annual responses in Table 2, *Estimated Annual Reporting Burden*, is based primarily on mandatory and voluntary adverse event reports electronically submitted to the Agency. The estimated total annual responses is based on initial reports. Followup reports, if any, are not counted as new reports. Based on our experience with adverse event reporting, we estimate that it will take a respondent 0.6 hour to submit a voluntary adverse event report via the SRP, 1 hour to submit a mandatory adverse event report via the SRP, and 0.6 hour to submit a mandatory adverse event report via the ESG (gateway-to-gateway transmission). Both mandatory and voluntary RFR reports must be submitted via the SRP. We estimate that it will take a respondent 0.6 hour to submit a RFR report, whether the submission is mandatory or voluntary.

The burden hours required to complete paper FDA reporting forms (Forms FDA 3500, 3500A, 1932, and 1932a) are reported under OMB control numbers 0910-0284 and 0910-0291. While we do not charge for the use of the ESG, respondents are required to obtain a public key infrastructure certificate to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from $20 to $30.

12b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $141,386,203 per year. We estimate that the average hourly wage for the employee preparing and submitting the report is equivalent to a GS-12/Step-1 level in the locality pay area of Washington-Baltimore in 2019, approximately $39.07/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to respondents to be $78.14/hour. Thus, the overall estimated cost incurred by the respondents is $141,386,203 (1,809,396 burden hours x $78.14/hr = $141,386,203.44).

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

Our internal assessment estimates that the cost for processing an electronic submission is $19.00 per report. The total annual responses (table 2) are estimated at 3,013,420 reports per year. Thus, $19.00 x 1,867,657 reports = $57,254,980 per year.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall increase of 688,547 hours and a corresponding increase of 1,145,763 responses. The majority of these adjustments is attributed to the shift in mandatory reports associated with medical devices (mandatory reports via the ESG), which had previously been counted under OMB Control 0910-0291, *MedWatch* paper reporting. We attribute the remaining adjustments to an increase in the number of submissions we have received over the last three years. We have also input the associated costs found at *Question 12b.* that, although were previously and are currently reported, were not uploaded to appear at www.reginfo.gov.

16. Plans for Tabulation and Publication and Project Time Schedule

No comprehensive statistical reporting, tabulation, or publication of the data are planned. However, we do plan to post redacted, publically available adverse event data on the FDA website that can be used by others for informational and analytic purposes.

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

Display of the OMB expiration date is provided as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.