Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal

0910-0645

SUPPORTING STATEMENT

Terms of Clearance: In accordance with 5 CFR 1320, the information collection request is approved for three years. However, OMB's action is currently limited to approval of the information collections associated with the Food Registry. We are providing placeholders of one hour that reflect OMB agreement that the planned development of the MedWatch system is consistent with the PRA. As the agency develops the other components of the MedWatch system and the specific instruments described in this request, it should consult with OMB, prior to implementation of new modules or revisions to the Food Registry modules, to determine whether further public notice is needed and/or the developments represent non-material/non-substantive changes. On or before the next request for an extension of OMB approval, FDA should also consider whether the usability of the system for voluntary reports from consumers and other entities that may not be familiar with FDA terminology can be improved to reduce burden and improve the utility of the information received by FDA. FDA should also consider improvements or revisions to the voluntary components of this collection that more clearly indicate to the respondent when their response is not mandatory. Finally, FDA is reminded that all information collections including those on websites, must display an OMB number and must provide the public with the information required in 5 CFR 1320.

Response:

Public notice for future rational questionnaires - The Food and Drug Administration (FDA) submitted the first rational questionnaire in 2009 with the initial information collection request. The Agency submitted the second and third rational questionnaires in 2010 as a non-material/non-substantive change, per the Terms of Clearance, after publishing a 30-day notice in the Federal Register for each. Thereafter, FDA decided that it was necessary to publish both 60- and 30-day notices for future proposed rational questionnaires. FDA solicited public comment on the fourth rational questionnaire proposed with this information collection request in a 60-day notice published in the Federal Register of September 14, 2012 (77 FR 56847) and in a 30-day notice published January 16, 2013. Future new rational questionnaires are being developed at this time and, as the questionnaires are finalized, FDA plans to invite public comment on each with 60- and 30-day notices.

Improving usability of the system for reports from voluntary reporting entities – 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. FDA developed the new rational questionnaire for voluntary tobacco product adverse event and product problem reports with the assistance of professional organizations and community interest groups and collected feedback during user acceptance testing. Voluntary reporters who find it too difficult to submit tobacco reports using the electronic system will be able to provide their information by telephone, or, by completing the paper MedWatch form approved under OMB control number 0910-0291 and submitting it via mail or FAX.

Indicating when a response is not mandatory – To indicate when a response is required or mandatory, the rational questionnaire displays a red asterisk immediately to the left of the question. The asterisk is explained at the top of the screen by the notation, "* = Required." Those questions appearing without the asterisk indicate that a response is optional.

Display of the OMB control number and the information required in 5 CFR 1320 – The OMB control number 0910-0645, the expiration date, and the burden statement information is displayed on the FDA website when a user accesses the rational questionnaire.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The FDA Safety Reporting Portal (the SRP) (formerly referred to as the MedWatch^{Plus} Portal and Rational Questionnaire) 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, the Agency needs 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 Agency 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, 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, 514.80, 600.80, 803.30, 803.40,803.50, 803.53, 803.56 and 1271.350(a)). Many of the adverse event reports submitted to FDA are currently filed in paper format using FDA Forms FDA 3500, 3500A, 1932, and 1932a, 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, approved under OMB control number 0910-0645.

We request the extension of OMB approval for the following collection of information requirements and four rational questionnaires available as variations of Form FDA 3800:

21 CFR 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56 and 1271.350(a) -- Reporting

Requires submission of an adverse event report to FDA, sets forth the information that the report is required to contain, the method of submission of the report, and the time within which the report must be submitted.

FDA also seeks to simplify the title of this collection and rename it "Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal."

The FDA Safety Reporting Portal Rational Questionnaires -

The term "Form FDA 3800" refers to the electronic system known as the Safety Reporting Portal or SRP. FDA currently has OMB approval to receive three types of adverse event reports electronically via the SRP using rational questionnaires. FDA sought comments on the extension of OMB approval for the existing three rational questionnaires, as well as comments on a proposed new fourth rational questionnaire that will be used for a safety reporting program being launched by the Center for Tobacco Products (CTP).

A. Reportable Food Registry Reports – **Combining/Incorporating Burden Hours From Control No. 0910-0709**

The Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) (FDAAA) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by creating a new 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 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) of the FD&C Act). The Secretary of Health and Human Services (the Secretary) has delegated to the Commissioner of FDA the responsibility for administering the FD&C Act, including section 417. To further the development of the RFR, section 417 of the FD&C Act required FDA to establish an electronic portal by which instances of reportable food ("RFR reports") must be submitted to FDA by responsible parties and may be submitted by public health officials. A "responsible party" is the person who submits the registration under section 415(a) of the FD&C Act (21 U.S.C. 350d) for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held. The RFR electronic portal was established in 2009 and approved under OMB control number 0910-0645.

The Congressionally identified purpose of the RFR is to provide "a reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health" (121 Stat. 965). The RFR reports are designed 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. FDA uses the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses.

On January 4, 2011, the President signed into law the FDA Food Safety Modernization Act (Public Law 111-353) (the legislation or FSMA). Section 211 of the legislation amended section 417 of the FD&C Act to require FDA to collect additional information in the Agency's RFR reports: (1) A description of the article of food; (2) affected product identification codes, such as universal product code (UPC), stock keeping unit, or lot or batch numbers sufficient for the consumer to identify the article of food; (3) contact information for the responsible party; and (4) any other information the Secretary determines is necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food. The amendment made by section 211 of FSMA took effect June 4, 2012, 18 months after the date of enactment. To comply with this statutory deadline, FDA initially obtained OMB approval of the additional collection of information requirements under the emergency processing provisions of the PRA under OMB control number 0910-0709. The new data improves the RFR's effectiveness in carrying out its purpose of tracking

patterns of adulteration in food and supporting FDA's efforts to target limited inspection resources to protect the public health. In this request for extension of OMB approval, FDA is combining the burden hours associated with OMB control number 0910-0709 with the burden hours approved under this OMB control number (0910-0645).

B. Reports Concerning Experience With Approved New Animal Drugs - **Unchanged**
Section 512(l) of the FD&C Act (21 U.S.C. 360b(l)) and § 514.80(b)) 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.

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. Post-approval 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. Collection of information using existing paper forms FDA 2301, 1932, and 1932a is approved under OMB control number 0910-0284. Alternatively, an applicant may choose to report adverse drug experiences and product/manufacturing defects electronically. Collection of this information electronically was approved in 2010 under OMB control number 0910-0645. 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. Pet Food Early Warning System - **Unchanged**
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.

FDA 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. The Pet Food Early Warning System is designed to identify adulteration of the pet food supply and outbreaks of illness associated with pet food to enable FDA to quickly identify, track and remove from commerce such articles of food. FDA uses the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses. In 2010, OMB approved the Pet Food Early Warning System component of the SRP under OMB control number 0910-0645, and FDA launched the rational questionnaire by which consumers may electronically report adverse events associated with pet food. The electronic submission data

elements to report adverse events associated with pet food remain unchanged in this request for extension of OMB approval.

D. Voluntary Tobacco Product Adverse Event and Product Problem Reports – **NEW RQ**

As noted, this information collection request seeks OMB approval for a proposed new, fourth rational questionnaire that will be used for a new safety reporting program being launched by the CTP to collect voluntary tobacco product adverse event and product problem reports.

FDA has broad legal authority under the FD&C Act to protect the public health. CTP's mission is to protect 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 (Public Law 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. At this time, FDA is proposing to collect 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 will contribute to 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 objective to obtain current, timely, and policy-relevant information to carry out our statutory functions. The FDA Commissioner 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 currently receives adverse event and product problem reports primarily via paper MedWatch forms, approved under OMB control number 0910-0291. MedWatch forms, although recently updated with field labels and descriptions to better clarify for reporters the range of reportable products, including tobacco products, do not specifically include questions relevant for the analysis of adverse events or product problems related to tobacco products. The proposed voluntary tobacco product adverse event and product problem rational questionnaire will include these specific questions. The questionnaire evolved with input from a National Institutes of Health team of human-factors experts, from other regulatory Agencies, and with extensive input from consumer advocacy groups and the general public. FDA is also working with the FDA Internet team to follow the Department of Health and Human Services Internet guidelines for Web design. FDA has and will continue to reach out to professional organizations and community interest groups to collect feedback during the user acceptance testing. The rational questionnaire will provide the user with detailed navigation instructions to include drop-down menus, lists of values, controlled vocabularies, and mouse over help where possible. In addition, CTP will issue guidance for the rational questionnaire. Finally, we note that users who are unable to submit reports using the electronic system will still be able to provide their information by paper form (by mail or FAX) or telephone.

The proposed voluntary tobacco product adverse event and product problem rational questionnaire requests the following information:

Introductory Information About the Submission

- Whether the submission is a new report, or a follow-up or amendment to a previously transmitted report.

Information About the Sender and the Affected Person

- Unless the sender wishes to remain anonymous, the name of and contact information for the person sending the report; and
- Unless the affected person wishes to remain anonymous, the name, contact information, and demographic information for the person who experienced the adverse event.

Details of Any Attachments

- The type of attachment and a description of it.

Tobacco Product Details

- Information about the product that is the subject of the report, such as the brand name, product name, UPC, and a description of the tobacco product or component;
- Information about the product or component purchase date and location; and
- Information about the manufacturer of the product or component.

Problem Summary

- Information about the product problem or adverse event, such as the date and duration of the problem or adverse event, a description of the use of the product, a description of the product problem or adverse event, and a description of the main symptoms or health problems.
- Information about the medical treatment received by the affected person, such as whether the person was taken to an emergency facility, a description of any medical testing or treatment performed, and the results of any tests;
- Information about any similar product problems or adverse events previously had by the affected person; and
- In the event of death, the date of death and the reported cause of death.

Other Products Used

- Information about the affected person's use of other tobacco products, alcohol, prescription medications, over-the-counter medications, vitamins, or dietary supplements.

The rational questionnaire will capture tobacco-specific adverse event and product problem information from voluntary 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. When FDA receives tobacco-specific adverse event and product problem information, it will use the information to assess and evaluate the risk associated with the product, and then FDA will take whatever action is necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

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 carry out its responsibilities, the Agency needs 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. The information is used by FDA 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, 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. 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 likely respondents include businesses engaged in the manufacture, processing, packing, holding or distribution of FDA-regulated products for consumption or to be marketed in the United States as well as individuals (consumers, health care providers, researchers, and Federal, State, and local public health officials). 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

There is no duplication of reporting in this information collection as a result of the mandatory adverse event reporting required by statute or regulation. To the best of FDA's knowledge, no other federal government agency is engaged in the collection of this information. In the event that we receive a report on a product that is not under FDA's 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

FDA estimates 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. FDA notes 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 to the agency and written responses to the agency 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.
Pet Food Early Warning System	This is a voluntary report. There is no required timeframe for submission.
Voluntary Tobacco Product Adverse Event and Product Problem Reports	This is a voluntary report. 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 September 14, 2012 (77 FR 56847) FDA published a 60-day notice requesting public comment on the proposed revision of this information collection. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The HIPAA Privacy 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. [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.

FDA provides no assurance of confidentiality to responsible persons who voluntarily decide, or are required, to submit a RFR report to FDA. Under section 417(h) of the FD&C Act, a record in the Reportable Food Registry is subject to a request under the Freedom of Information Act (FOIA) (5 U.S.C. 552), except that FDA registration numbers are protected from disclosure as provided by section 415(a)(4) of the FD&C Act. In addition, 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 the agency's regulations (21 CFR part 20). To the extent 21 CFR 20.64 applies, FDA will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

The rational questionnaire and the voluntary paper report forms (e.g., Form FDA 3500, Form FDA 1932a) used by healthcare professionals and consumers to report directly to the FDA informs the reporter that their identity, including self-reporters, will be shared with the manufacturer of the product unless they indicate otherwise during the completion of the rational questionnaire report

view or checking box G5 on the Form FDA 3500 or the box on the top left on Form FDA 1932a. This limited disclosure will not trigger release of such information under FOIA.

With regard to Reports Concerning Experience with Approved New Animal Drugs, confidentiality of the information submitted under these reporting requirements is protected under 21 CFR 514.11 and 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. Further, under the terms of the Freedom of Information Act, the veterinarian's name, address, and phone number, and the owner's name, etc., reported on Form FDA 1932 cannot be made available to a public request.

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

FDA estimates 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	1,513	1	1,513	0.6 (36 minutes)	908
Mandatory Adverse Event Report via the SRP (Other than RFR Reports).	3800	636	1	636	1	636
Mandatory Adverse Event Report via the ESG (Gateway-to-Gateway transmission).	3800	1,491,228	1	1,491,228	0.6 (36 minutes)	894,737
Mandatory and Voluntary RFR Reports via the SRP.	3800	1,413	1	1,413	0.6 (36 minutes)	848
Total						897,129

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

The Agency's 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 are based on initial reports. Follow-up reports, if any, are not counted as new reports. Based on its experience

with adverse event reporting, FDA estimates 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. FDA estimates that it will take a respondent 0.6 hour to submit a RFR report, whether the submission is mandatory or voluntary.

Voluntary adverse event reports submitted via the SRP (other than RFR Reports) include reports associated with pet food (the Pet Food Early Warning System) and the new tobacco product adverse event and product problem reports. The Center for Veterinary Medicine (CVM) received 845 pet food adverse event reports in 2010; 1,293 reports in 2011; and 471 reports in the first 4 months of 2012, and estimates that for the full 12 months of 2012 it will receive 1,413 reports. Based on this experience, CVM estimates that it will receive, on average, 1,413 pet food reports annually over the next 3 years. CTP estimates that it will receive approximately 100 voluntary tobacco product adverse event and product problem reports annually, after implementation of electronic reporting. CTP received 27 reports in 2010, 30 reports in 2011, and 22 reports in the first half of 2012, and estimates that for the full 12 months of 2012 it will receive over 40 reports. Based on this experience and an expectation that reporting will increase once electronic reporting is launched, CTP estimates that it will receive, on average, 100 voluntary adverse event and product problem reports annually over the next 3 years. Thus, FDA estimates that over the next 3 years it will receive annually 1,513 voluntary adverse event reports submitted via the SRP, with a burden of 907.8 hours, rounded to 908 hours, as reported in table 2, row 1 (1,413 + 100 = 1,513).

Mandatory adverse event reports submitted via the SRP (other than RFR Reports) include reports of adverse animal drug experiences and product/manufacturing defects associated with approved NADAs and ANADAs. CVM received 144 such adverse event reports in 2010, 537 reports in 2011, and 212 reports in the first four months of 2012, and estimates that for the full 12 months of 2012 it will receive 636 reports. Based on this experience, CVM estimates that it will receive, on average, 636 reports of adverse drug experiences and product/manufacturing defects associated with approved NADAs and ANADAs annually over the next 3 years. Thus, FDA estimates that over the next 3 years it will receive annually 636 mandatory adverse event reports submitted via the SRP, with a burden of 636 hours, as reported in table 2, row 2.

Adverse event reports submitted via the ESG include reports of adverse experiences related to drugs, biological products, and medical devices, as well as, adverse animal drug experiences and product/manufacturing defects associated with approved NADAs and ANADAs. FDA received 586,229 such adverse event reports in 2010; 850,161 reports in 2011; and 497,076 reports in the first 4 months of 2012; and estimates that for the full 12 months of 2012 it will receive 1,491,228 reports. Based on this experience, FDA estimates that it will receive, on average, 1,491,228 adverse event reports submitted via the ESG, with a burden of 894,736.8 hours, rounded to 894,737 hours, as reported in table 2, row 3.

FDA estimates that over the next 3 years it will receive annually 1,413 mandatory and voluntary RFR Reports submitted via the SRP, as reported in table 2, row 4. The Center for Food Safety and Applied Nutrition (CFSAN) received 845 such adverse event reports in 2010; 1,293 reports in 2011; and 471 reports in the first four months of 2012; and estimates that for the full 12 months of 2012 it will receive 1,413 reports. Based on this experience, CFSAN estimates that it will receive, on

average, 1,413 mandatory and voluntary RFR Reports submitted via the SRP annually over the next 3 years, with a burden of 847.8 hours, rounded to 848 hours, as reported in table 2, row 4.

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 FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure certificate in order 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 $64,377,977 per year. FDA estimates that the average hourly wage for the employee preparing and submitting the report would be equivalent to a GS-12/Step-1 level in the locality pay area of Washington-Baltimore in 2012, approximately $35.88/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $71.76/hour. Thus, the overall estimated cost incurred by the respondents is $64,377,977 (897,129 burden hours x $71.76/hr = $64,377,977).

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's 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 1,494,790 reports per year. Thus, $19.00 x 1,494,790 reports = $28,401,010 per year.

15. Explanation for Program Changes or Adjustments

The burden estimate for the subject ICR was inadvertently over-reported in ICRAS/ROCIS in 2010, when the second and third rational questionnaires were approved as a non-material/non-substantive change. The over-reporting was caused by erroneously doubling the number of ICs from 6 to 12. This error was corrected by removing the 6 duplicative ICs. To further refine the reporting burden, 3 of the previous ICs that were segregated on the basis of mandatory versus voluntary reporting have been consolidated into one as appropriate. As submitted, the subject ICR now reflects a total of 4 information collections and also incorporates the burden reflected and approved under OMB Control No. 0910-0709. The latter ICR was initially obtained in May of last year to allow FDA to implement provisions of the Food Safety and Modernization Act. Accordingly, because of this consolidation, the Agency has submitted a discontinuation request for OMB Control No. 0910-0709 as it is now included in the instant ICR.

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

We are not seeking approval to not display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.