On April 1, 2013 (78 FR 19492), FDA announced the availability of a draft version of this guidance. All comments received during the comment period for the draft guidance have been reviewed and, where appropriate, incorporated into this guidance. As a result of the public comments, information has been added to provide clarity on the process for requesting meetings, including identifying the appropriate meeting type, and the data expectations to support the appropriate meeting type.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on formal meetings between FDA and biosimilar biological product sponsors or applicants. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

### II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0802.

### III. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov*.

Dated: November 13, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–29455 Filed 11–17–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0921]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Reporting; Electronic Submissions

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the use of the FDA Electronic Submission Gateway (ESG) and the Safety Reporting Portal (SRP) to collect adverse event reports and other safety information for FDA-regulated products.

**DATES:** Submit either electronic or written comments on the collection of information by January 19, 2016.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2012–N–0921 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets

Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

## II. Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal—21 CFR 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 1271.350 and Part 803—OMB Control Number 0910–0645—Revision

The SRP and the 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)). While adverse event reports submitted to FDA in paper format using Forms FDA 3500, 3500A, 1932, and 1932a, are approved under OMB control numbers 0910–0284 and 0910–0291, this notice solicits comments on adverse event reports filed electronically via the SRP and the ESG, and currently approved under OMB control number 0910–0645.

## III. The FDA Safety Reporting Portal Rational Questionnaires

FDA currently has OMB approval to receive several types of adverse event reports electronically via the SRP using rational questionnaires. In this notice, FDA seeks comments on the extension of OMB approval for the existing rational questionnaires; the proposed revision of the existing rational questionnaire for dietary supplements; the proposed revision of the existing rational questionnaire for tobacco products; a proposed new rational questionnaire that will be used for a new safety reporting program for clinical trials and/or investigational use by the Center for Tobacco Products (CTP); and proposed new rational questionnaires that will be used for food, infant formula, and cosmetic adverse event reports.

### *A. Reportable Food Registry Reports*

The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) (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 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. 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). 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. FDA's 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, an applicant 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 the 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*

As noted, this notice seeks comments on two items: (1) A revision to the existing rational questionnaire utilized by consumers and concerned citizens to report tobacco product adverse event or product problems, and (2) a proposed new rational questionnaire that will be used for a new safety reporting program for clinical trials and/or investigational use by CTP.

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. At this time, 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 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)).

FDA's 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. The original 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. The revised CTP questionnaire along with the proposed new Investigator questionnaire build on the foundation of the original rational questionnaire to make the report's data more useful, analyzable, and specific. The change from the original to the new questionnaire is simply a change in wording, to make the question more understandable and specific. In other instances, alterations were made to the long list of values to choose from by the end user in order to include values more pertinent to CTP's current and future data collection needs. In still other instances, questions were removed altogether in an effort to streamline the questionnaire and make it more user-friendly. 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 new rational questionnaire will be used by tobacco product investigators in clinical trials with investigational tobacco products. In addition to the information collected by the existing rational questionnaire for tobacco products, the proposed rational questionnaire will collect 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 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.

*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, FDA 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.

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 followup 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. However, we are proposing to add a new voluntary question on the mandatory report rational questionnaire and a new voluntary question on the voluntary report rational questionnaire. The text of the new questions is provided in table 1. Finally, we are proposing to change the following data elements from a text box method of response to an individual question and answer method: Race and known allergies.

TABLE 1—PROPOSED NEW QUESTIONS ON THE DIETARY SUPPLEMENT RATIONAL QUESTIONNAIRE

| Text of new question | Is response mandatory or voluntary? |
|---|---|
| Mandatory Report—In the Contact Information section, we propose to add, ''Please provide contact information for you, the person who is filling out this report.'' | Voluntary, and only displayed if the person filling out the report is reporting on behalf of a responsible person, such as a contractor, and has not created an account on the SRP. |
| Voluntary Report—In the Product Information section, we propose to request the ingredients of the suspect and concomitant product(s), as provided on the label of the product(s). | Voluntary. |

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. OMB approved the extension of the 0910–0635 collection of information in February 2013. OMB approved the electronic submission of dietary supplement adverse event reports via the SRP under OMB control number 0910–0645 in June 2013. Burden hours are also reported under OMB control number 0910–0291 reflecting the submission of dietary supplement adverse event reports on the paper MedWatch form, Form FDA 3500A.

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

We are planning proposed new rational questionnaire functionality that will be used for food, infant formula, and cosmetic adverse event reports. Currently, voluntary adverse event reports for such products are submitted on Form FDA 3500, which is available as a fillable pdf form. However, we have not 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.

TABLE 2—NEW QUESTIONS ON THE PROPOSED FOOD, INFANT FORMULA, AND COSMETICS RATIONAL QUESTIONNAIRES FOR BOTH SUSPECT AND CONCOMITANT PRODUCTS

| Text of new question | Is response mandatory or voluntary? |
|---|---|
| For food products: | Voluntary. |
| "Is this a medical food?" | |
| "If so, what was the diagnosis or reason for use?" | |
| "How was the product prepared?" | |
| For infant formula products: | Voluntary. |
| "What form of the product was used: Concentrate, powder or ready to serve?" | |
| Is this a specialized infant formula?" | |
| "If so, what was the diagnosis or reason for use?" | |
| "How was the product prepared?" | |
| "What type of water was used to prepare the formula?" | |
| For cosmetic products: | Voluntary. |
| "Do you have existing skin conditions?" | |
| "How soon did symptoms develop after using the product? | |
| "Did the intensity of the reaction get worse with time? | |
| "Where did the reaction develop?" | |
| "What treatments were sought for this adverse event?" | |
| "What ingredient do you suspect caused the adverse event?" | |
| "Has the problem resolved?" | |
| "Does the product label contain a warning or caution statement?" | |

## IV. Information Collection Burden Estimate

*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.

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

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Voluntary Adverse Event Report via the SRP (Other than RFR Reports) | 1,786 | 1 | 1,786 | 0.6 (36 minutes) | 1,072 |
| Mandatory Adverse Event Report via the SRP (Other than RFR Reports) | 636 | 1 | 636 | 1.0 | 636 |
| Mandatory Adverse Event Report via the ESG (Gateway-to-Gateway transmission) | 1,864,035 | 1 | 1,864,035 | 0.6 (36 minutes) | 1,118,421 |
| Mandatory and Voluntary RFR Reports via the SRP | 1,200 | 1 | 1,200 | 0.6 (36 minutes) | 720 |
| Total | | | | | 1,120,849 |

[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 3, 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. Followup 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.

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.

Dated: November 12, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–29407 Filed 11–17–15; 8:45 am]

**BILLING CODE 4164–01–P**