United States Food and Drug Administration

Electronic Submission Process for Voluntary Allegations
to the Center for Devices and Radiological Health

OMB Control No. 0910-0769

SUPPORTING STATEMENT

Terms of Clearance: "None"

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

   Section 301 of the Public Health Service Act (24 U.S.C. 241) is the authorizing statute.

   Historically the Center for Devices and Radiological Health (CDRH) has received allegations about medical devices via phone calls, emails, and even conversationally during formal and informal meetings and conferences. All device complaints are voluntary; there are no regulatory requirements for submitting allegations.

   CDRH has established an electronic process for submitting allegations for two reasons: (1) to improve the consistency and quality of complaint data received; (2) to enhance the reporter's ability to convey allegations and concerns to CDRH; and (3) facilitate CDRH's ability to detect and intervene to mitigate significant device issues in a timely fashion.

   There is no statutory or regulatory requirement for the submission of medical device allegations. Thus, no data collection form has been established for medical device allegations. The electronic submission structure defines a few "mandatory" fields so that CDRH could follow-up with the allegations reporter when necessary to more fully understand the nature of the health risks associated with the submitted allegations.

2. Purpose and Use of the Information Collection

   Respondents to this information are individuals or households, private sector businesses or other for-profit, not-for-profit institutions, State, local or tribal governments, and Federal government.

   CDRH uses allegations as potential signals of emerging risks associated with medical devices and radiological health products. Allegations are evaluated and given a risk assessment score which helps define how to best make use of the information provided. Individual or clusters of allegations have been used to support regulatory action directed towards product manufactures, importers or distributors, and have clarified the need for educational outreach to users. For example, allegations about recalled devices being offered for sale on eBay led to CDRH collaboration with the management of eBay USA

to identify and remove postings for sale of recalled devices that should no longer be made available for sale or distribution in the United States.

3. Use of Improved Information Technology and Burden Reduction

Since, prior to the electronic submission process, there was no existing standard process for submitting allegations, reporters were often at a loss of who to contact, where to send communications, and what information to provide. By having a standard electronic process we reduce the time associated with trying to find the right contact and learning how to submit a complaint. The electronic process also enables reporters to skip through details that don't apply, and enables reporters to review the submission before transmitting. There is no cost to reporters using the electronic submission process.

FDA estimates that approximately 95% of future reporters will use electronic means to submit their allegation to CDRH.

4. Efforts to Identify Duplication and Use of Similar Information

Review of FDA guidance documents, websites and FR notices confirms that the electronic submission of allegations to CDRH represents a unique opportunity for reporters. Allegations are reports of actual or potential violations of law or regulation. No other program or process exists for the collection of this type of information.

5. Impact on Small Businesses or Other Small Entities

This data collection would not impact small businesses other than when an individual employee of a small business wanted to voluntarily share an allegation with CDRH. The allegation submission process will enable reporters to provide whatever information is available and allow reporters to skip over elements (or fields) for which information is not known.

6. Consequences of Collecting the Information Less Frequently

Because an allegation relates to a specific device and specific situation, it would be most accurate to say that allegation submission represents a one-time collection.

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

There are no special circumstances for this collection of 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), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of February 10, 2020 (85 FR 7562). Two comments were received.

The first comment was not relevant to the information collection.

The second comment stated that the rule does not state whether people submitting allegations of regulatory misconduct are required to redact their contact information.

We disagree with the comment. Anyone may file a complaint reporting an allegation of regulatory misconduct. The FDA encourages people submitting allegations to include supporting information and contact information in case additional information is needed for the FDA to understand the allegation and act on the report; however, you can choose to submit a report anonymously. The FDA will not share your identity or contact information with anyone outside the FDA unless required to do so by law, regulation, or court order.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g. point of contact). The PII submitted via online portal is name, work address, work email address.

FDA further determined that although PII is collected the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of the individuals.

FDA does assure that information about the reporter will be maintained in compliance with the FOIA. The submission process will enable reporters to submit anonymously if desired. Reports are maintained electronically within FDA equipment and databases and kept secure per established Agency document management and security processes.

This process would not require use of an IRB.

11. Justification for Sensitive Questions

The electronic submission of an allegation does not generally involve the collection of any sensitive information. Allegations received by FDA are not routinely made public, though may be required to be released and would be managed per the FOIA.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Electronic submission of voluntary allegations to CDRH	1,600	1	1,600	0.25 (15 minutes)	400

12b. Annualized Cost Burden Estimate

The electronic submission of an allegation to CDRH is a voluntary action; no professional cost can be assigned to this activity.

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There is no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA estimates that a total of 3 full time equivalent (FTE) positions are needed for the collection of information. Based on a cost of $270,305 per position (which is the agency's projected average cost of an FTE including benefits*), the estimated annual Federal cost is $810,915.

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2018, as provided by agency economists.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall increase of 225 hours and a corresponding increase of 900 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

16. Plans for Tabulation and Publication and Project Time Schedule

These information collection requirements will not be published, tabulated or manipulated (i.e., the results are summarized, segmented, or altered).

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

FDA is not seeking approval to not display the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.