Electronic Submission Process for Voluntary Allegations
to the Center for Devices and Radiological Health
0910-NEW
SUPPORTING STATEMENT

Terms of Clearance: "None"

A. Justification

1. Circumstances Making the Collection of Information Necessary

   Section 301 of the Public Health Service Act (24 U.S.C. 241) as 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 seeks to establish 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.

   The electronic collection of medical device allegations does not relate in any way to the American Recovery and Reinvestment Act of 2009 (ARRA). Commonly referred to as the Stimulus or The Recovery Act, was an economic stimulus package enacted by the 111th United States Congress in February 2009 and signed into law on February 17, 2009, by President Barack Obama.

2. Purpose and Use of the Information Collection

   Individuals or households, Private Sector (business or other for-profit, not-for-profit institution, or a farm), 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 US.

3. Use of Improved Information Technology and Burden Reduction

   Since there is no existing standard process for submitting allegations and reporters are 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 burden associated with trying to find the right contact and learning how to submit a complaint. The electronic process will also enable reporters to skip through details that don't apply, and will enable reporters to review the submission before transmitting. There would be no fiscal cost to reporters using the electronic submission process.

   FDA estimates that approximately 95% of future reporters will use the available 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 onetime 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 May 6, 2013 (78 FR 26373). No comments were received.

   There was no outside consultation with industry, as that would not be applicable for voluntary allegation submissions.

As there is no obligation for the submission of allegation, it would not seem necessary or useful to obtain consultation.

9. Explanation of Any Payment or Gift to Respondents

There will be no remuneration for the submission of allegation to CDRH.

10. Assurance of Confidentiality Provided to Respondents

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 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					
Allegation Reporting Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
	700	1	700	.25 (15 minutes)	175

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 and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

This collection is part of the normal operating procedures of CDRH and thus there are no costs associated with this activity. However, we estimate that operational expenses for support staff at one FTE at a grade 13 grade 5 at $100,904 per annum.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

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.