UNITED STATES FOOD & DRUG ADMINISTRATION

Allegations of Regulatory Misconduct Voluntarily Submitted to the Center for Devices and Radiological Health

OMB Control No. 0910-0769 – Extension

SUPPORTING STATEMENT **Part A – Justification**:

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of section 301 of the Public Health Service Act (42 U.S.C. 241). Historically, under this authority, FDA's Center for Devices and Radiological Health (CDRH) has accepted allegations about medical devices via phone calls, emails, and even conversationally during formal and informal meetings and conferences. Accordingly, to improve the consistency and quality of the information received; to enhance respondents' ability to convey allegations and concerns to CDRH; and to facilitate CDRH's ability to detect and intervene to mitigate significant device issues in a timely fashion, we have established a process for the public submission of allegations of regulatory misconduct. Submissions are voluntary, however, to streamline our evaluation process we have developed an electronic format for certain data elements. As determined appropriate, CDRH may follow-up on the allegation to more fully understand the nature of the health risks associated with the report. We are therefore requesting extension of OMB approval for the collection of information regarding allegations of regulatory misconduct voluntarily submitted to CDRH, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Respondents to the information are individuals or households, private sector businesses or other for-profit, not-for-profit institutions, State, local or tribal governments, or anyone submitting an allegation of regulatory misconduct associated with a medical device. We use the information to help identify 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 limited resources. 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.

3. Use of Improved Information Technology and Burden Reduction

To assist respondents with the information collection, we maintain a website at https://www.fda.gov/medical-devices/medical-device-safety/reporting-allegations-regulatory-misconduct that includes instruction on submitting information. Allegations of regulatory misconduct associated with medical devices may be submitted by email to CDRHDeviceAllegations@fda.hhs.gov, or by regular mail addressed as follows:

Attention: *Allegations of Regulatory Misconduct Team*
Office of Regulatory Programs
Center for Devices and Radiological Health
Food and Drug Administration
WO Bldg. 66 RM 1523
10903 New Hampshire Ave
Silver Spring, MD 20993.

4. Efforts to Identify Duplication and Use of Similar Information

   We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

   The information collection should impose no undue burden on small entities.

6. Consequences of Collecting the Information Less Frequently

   The information collection is voluntary.

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

   We published a 60-day notice inviting public comment on the proposed information collection in the *Federal Register* of June 12, 2023 (88 FR 38061). Two comments were received. While one comment appeared to question the purpose of the information collection, the second comment supported FDA activities regarding the reporting of information covered by the collection. Neither comment suggested that we revise our burden estimate, but included suggestions on how our submission form might be improved. In response, we are revising the submission form using asterisks to indicate more clearly which fields are required to complete the submission versus non-required fields. The form has also been updated to allow submission of the company's website information.

   Another comment noted that current procedures do not allow for complete anonymity when submitting allegations of regulatory misconduct to FDA. The comment suggests changing the submission process to allow submission of attachments to the form, rather than via separate email. While we have not made changes regarding the submission process at this time, we appreciate these suggestions and continue to consider enhancements and updates to our systems as our limited resources permit. We recognize that confidentiality is an important concern. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible

disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

Finally, one comment expressed concern regarding verification by FDA of the accuracy and validity of the information (allegations) submitted. Allegations of regulatory misconduct related to medical devices are reviewed by CDRH. CDRH prioritizes the review of allegations based on the level of potential risks, within the context of an overall benefit-risk profile, to patients, and takes responsive action accordingly. We note, however, that subsequent questions or inquiry intended to clarify information submitted is not considered a collection of information under the PRA (see 5 CFR 1320.3(h)(9)) subject to OMB review and approval.

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

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), the PII submitted via FDA web page (Allegations of Regulatory Misconduct Form) is name and email address of the respondent, and we have determined that the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate webpage design, FDA limits submission fields and minimizes the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

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 Cost

12a. Annualized Hour Burden Estimate:

Table 1.--Estimated Annual Reporting Burden					
Electronic Submissions	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Allegations of regulatory misconduct to CDRH	2,500	1	2,500	0.25 (15 minutes)	625

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

14. Annualized Cost to the Federal Government

FDA estimates that four full time equivalent (FTE) positions are needed for the administration of the information collection. Based on an internal cost model, we assume a fully-loaded cost of $297,561 per position. We calculate annual Federal costs to be $1,190,244.

15. Explanation for Program Changes or Adjustments

We have increased our estimate of burden by 900 responses and 225 hours. We attribute the adjustment to improved efficiencies regarding the tracking of submissions.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collection will not be published or tabulated.

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

FDA will display the expiration date as required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.