4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-1095]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0769. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

OMB Control Number 0910-0769--Extension

This information collection request collects information voluntarily submitted to the Center for Devices and Radiological Health (CDRH) on actual or potential health risk concerns about a medical device or radiological product or its use. Because, prior to the establishment of the electronic submission process for voluntary allegations to CDRH, there had been no established guidelines or instructions on how to submit an allegation to CDRH, allegations often contained minimal information and were received via phone calls, emails, or conversationally. CDRH has established a consistent format and process for the submission of device allegations that enhances our timeliness in receiving, assessing, and evaluating voluntary allegations. The information provided in the allegations received by CDRH may be used to clarify the recurrence or emergence of significant device-related risks to the general public and the need to initiate educational outreach or regulatory action to minimize or mitigate identified risks.

In the *Federal Register* of February 10, 2020 (85 FR 7562), we published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments.

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. FDA encourages people submitting allegations to include supporting information and contact information in case additional information is needed for FDA to understand the allegation and act on the report; however, you can choose to submit a report anonymously. FDA will not share your identity or contact information with anyone outside FDA unless required to do so by law, regulation, or court order.

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

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. 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

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

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.

Dated: August 26, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

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