

UNITED STATES FOOD AND DRUG ADMINISTRATION

Reporting and Recordkeeping for Electronic Products – General Requirements

OMB Control No. 0910-0025

**Request for Non-Substantive/Non-Material Change:**

The Food and Drug Administration (FDA, us, we, or the agency) is requesting a non-substantive change to support its electronic product radiation control program, as directed by Sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360ii through 360ss). We believe this change request is consistent with OMB’s guidance in its PRA flexibility memorandum of July 22, 2016 (see p.5, *Example of Use of Non-Substantive Changes for Certain Web-based or Similar Applications*).

Changes to OMB Control No. 0910-0025: 21 CFR part 1002.20 requires manufacturers of electronic products to report to FDA the circumstances, products involved, nature and magnitude of exposure, and remedial actions taken concerning any accidental radiation occurrence event involving their electronic products. Consumers/the general public can also report accidental radiation occurrences to the agency for the purposes of public safety monitoring. To obtain this information from manufacturers and consumers/the general public, FDA utilizes form FDA 3649 “Accidental Radiation Occurrence Report” (ARO), as described on the following agency webpage: <https://www.fda.gov/radiation-emitting-products/radiation-safety/report-problem>. form FDA 3649, along with other information collections involving general reporting and recordkeeping requirements for electronic products, is currently approved under OMB Control No. 0910-0025.

Currently, form FDA 3649 is available as a portable document format (pdf) file on the FDA website, which may be submitted to the agency via physical mail or electronically using the Center for Devices and Radiological Health (CDRH) eSubmitter software application.

As encouraged by OMB’s PRA flexibility memorandum of July 22, 2016, FDA is proposing non-substantive/non-material updates to form FDA 3649, in order to offer an abbreviated webform for consumers/respondents from the general public. The proposed webform, form FDA 3649C will consolidate and remove fields from the existing form FDA 3649 to exclude information that may not be readily available to consumers, while modernizing data collection to ensure that respondents can provide the requested information in a least-burdensome manner. The proposed webform will not request that respondents submit, disclose, or maintain any additional information as compared to the current form FDA 3649. Once approved, the webform will be accessible along with the current form FDA 3649 via the agency’s website, which will be revised to indicate that consumers/respondents from the general public may use the abbreviated webform to submit this information.

After an analysis of the proposed form FDA 3649C, we have made the following adjustments to our currently approved burden estimate, based on the anticipated time to complete the

abbreviated webform (0.25 hours) and the proportion of respondents who are members of the general public (approximately 10 out of 75 total respondents).

The reporting burden for accidental radiation occurrence reports appears in the currently approved ICR as:

Activity/ 21 CFR Section	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (hrs.)	Total Hours
Accidental radiation occurrence reports —1002.20	3649—ARO	75	4	300	2	600

The adjustment in burden below represents a decrease in burden of 1.75 hours for each general public respondent submitting via the new abbreviated webform, as compared to the approved form FDA 3649. The second line item represents the shortened form.

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity/ 21 CFR Section	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (hrs.)	Total Hours
Accidental radiation occurrence reports —1002.20	3649	65	4	260	2	520
Consumer accidental radiation occurrence reports —1002.20	3649C	10	1	10	0.25	3
Total		75		270		523

<sup>1</sup> Numbers have been rounded.

**Submitted: June 2024**