Postmarket Surveillance of Medical Devices—21 CFR Part 822

OMB Control Number 0910–0449—Extension

This information collection supports FDA regulations. Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) authorizes FDA to require a manufacturer to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute. The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides instructions to manufacturers, so they know what information is required in a PS plan submission. FDA reviews PS plan submissions in accordance with 21 CFR 822.15 through 822.19 of the regulation, which describe the grounds for approving or disapproving a PS plan. In addition, the PS regulation provides instructions to manufacturers to submit interim and final reports in accordance with 21 CFR 822.38. To assist respondents with understanding the applicable statutory and regulatory requirements, we also developed the interpretive agency guidance entitled, ''Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act'' (October 2022) (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-surveillance-under-section-522-federal-food-drug-and-cosmetic-act*). Respondents to this collection of information are those manufacturers that require PS of their products.

In the **Federal Register** of June 6, 2025 (90 FR 25318) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 822.9 and 822.10; PS submission	3	1	3	120	360
§ 822.21; Changes to PS plan after approval	8	1	8	40	320
§ 822.28; Changes to PS plan for a device that is no longer marketed	1	1	1	8	8
§ 822.29; Waiver	1	1	1	40	40
§ 822.30; Exemption request	1	1	1	40	40
§ 822.38; Periodic reports	35	3	105	40	4,200
Total					4,968

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 822.31; Manufacturer records	3	1	3	20	60
§ 822.32; Investigator records	9	1	9	5	45
Total	105				

[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 increase of 1,890 total burden hours and a corresponding increase 45 total annual responses. This increase is based on internal FDA tracking data. The number of respondents varies annually, subject to the number of original plans, plan changes, and interim and final reports (which are dependent on enrollment progress for each study) received by FDA.

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2025–23630 Filed 12–22–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OS–0990–0488]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, Administration for Strategic Preparation and Response (ASPR), U.S. Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Administration for Strategic Preparation and Response (ASPR), HHS, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the information collection request (ICR) must be received on or before February 23, 2026.

ADDRESSES: Submit your comments to *wayland.coker@hhs.gov* or by calling (202) 875–1103.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier OS–0990–0488, and project title for reference, and send to Wayland Coker, the ASPR Center for Industrial Base Management and Supply Chain, Chief Supply Chain Strategist, *wayland.coker@hhs.gov,* or call (202) 875–1103.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and

utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Ensure a Strong Public Health Supply Chain Through Streamlined Oversight and American Priorities.

Type of Collection: Extension.

Office of Management and Budget (OMB) No. 0990–0488—Administration for Strategic Preparedness and Response—Center for Industrial Base Management and Supply Chain.

Abstract

HHS, Administration for Strategic Preparedness and Response (ASPR) is seeking approval by OMB on an extension of the existing clearance (OMB Control Number: 0990–0488, Expiration Date: March 31, 2026). HHS is working with the White House and across the federal interagency to launch a multiyear implementation involving the identification and coordination of measurable activities across the United States government, state, local, tribal, and territorial (SLTT) jurisdictions, and private sector partners. Cross-sectoral engagement is the underpinning of many of the interdependent implementation activities. For example, one such activity involves information collection from SLTT partners on facility, local, and state stockpiling plans to ensure coordinated plans are in place for a future public health emergency. Potential engagements include, and are not limited to, surveys, stakeholder meetings, requests for information (RFI), town hall meetings, and workshops. With each of these different mechanisms of engagement, there is a varied frequency ranging from single engagements to regularly recurring meetings.

In 2025, the White House capacity and strengthening the public health supply chain through a series of executive actions focused on reducing foreign dependency, enhancing domestic manufacturing capacity, and improving emergency preparedness. This includes the establishment of the Strategic Active Pharmaceutical Ingredients Reserve (SAPIR), directed by HHS and managed through ASPR, to ensure a secure, domestic supply of essential drug components. The administration has also invoked Section 232 of the *Trade Expansion Act* of 1962 to assess whether reliance on imports of materials such as processed critical minerals and copper poses a national security risk, including risks to the production of pharmaceuticals and other medical countermeasures. These coordinated efforts reflect a broader federal strategy to increase the resilience, agility, and visibility of the public health supply chain in support of future emergency response operations. To support White House priorities, HHS seeks a 3-year extension to its Paperwork Reduction Act clearance and will engage with SLTT, trade groups, mixed cross-sector audiences, non-governmental organizations, manufacturers, academia, healthcare providers and facilities, and local communities.

ESTIMATED ANNUALIZED BURDEN TABLE OVER THREE YEARS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Private sector companies, SLTT, Trade groups and associations, NGOs, Manufacturers, distributors, Academia, Healthcare delivery providers/facilities, Public, USG Supply chain inventory holders, Biopharmaceutical industry, Biotechnology development companies, Communities, GPOs, standards development organizations, logistics, third party contractors, purchasing organizations, professional associations/societies, Mixed cross-sector audience, labor unions, workforce training providers, organizations, state and local workforce boards, and individuals who rely on wearable medical countermeasures.	Informed consent	32,800	1	0.08	2,624
	Demographics standardized questionnaire with decision logic allowing some questions to be omitted.	32,800	1	0.25	8,200
	Cognitive questionnaire	5,990	1	8	47,920
	Formative interviews and focus groups	6,600	2	4	52,800
	Town halls and public meetings	10,200	2	8	163,200
	Supply chain questionnaires	1,000	156	0.5	78,000
	Knowledge-based questionnaires	6,000	1	0.5	3,000
	Interviews and focus groups	3,000	1	1	3,000
	Instrumented information collection	160	1	0.5	80
Total Burden Hours Over Three Years					358,824

Catherine Howard,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2025–23759 Filed 12–22–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

RIN 0955–AA13

Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care

AGENCY: Office of the Deputy Secretary and Assistant Secretary for Technology Policy (ASTP) and Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP/ONC), Department of Health and Human Services.

ACTION: Request for information.

SUMMARY: The HHS Office of the Deputy Secretary in collaboration with ASTP/ONC has published this Request for Information (RFI) to seek broad public comment on what HHS can do to accelerate the adoption and use of AI as part of clinical care.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, by February 23, 2026.

ADDRESSES: You may submit comments, identified by ''HHS Health Sector AI RFI,'' by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. *http://www.regulations.gov.*
- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Assistant Secretary for Technology Policy and the Office of the National Coordinator for Health Information Technology, Attention: Request for Information: HHS Health Sector AI RFI, Mary E. Switzer Building,