

qualifications necessary to contribute to the accomplishments of the objectives of the ACET. Nominees will be selected on the basis of their expertise in public health, epidemiology, immunology, infectious diseases, pulmonary disease, pediatrics, tuberculosis, microbiology, or preventive health care delivery. Expertise within TB includes having had TB disease or being the parent of a child with TB disease. Federal employees will not be considered for membership. Members may be invited to serve for up to four-year terms. Selection of members is based on candidates' qualifications to contribute to the accomplishment of ACET objectives.

Department of Health and Human Services (HHS) policy stipulates that committee membership be balanced in terms of points of view represented and the committee's function. Appointments shall be made free from discrimination on the basis of race, color, religion, sex, national origin, age, disability, or other protected status, consistent with applicable law and Departmental policy. Nominees must be U.S. citizens and cannot be full-time employees of the U.S. Government. Current participation on Federal workgroups or prior experience serving on a Federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees, requiring the filing of financial disclosure reports at the beginning of and annually during their terms. The Centers for Disease Control and Prevention (CDC) reviews potential candidates for ACET membership each year and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment near the start of the term in July, or as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year. Candidates should submit the following items:

- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, and email address).

- At least one letter of recommendation from person(s) not employed by HHS. Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (*i.e.*, CDC,

National Institutes of Health, Food and Drug Administration).

- A biographical sketch of the nominee (500 words or fewer).

Nominations may be submitted by the candidate or by the person/organization recommending the candidate. CDC will collect and retain nominations received for up to two years to create a pool of potential ACET nominees. When a vacancy occurs, CDC will review nominations and may contact nominees at that time.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7129]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Event Program for Medical Devices: (Medical Product Safety Network (MedSun))

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 November 9, 2026.

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 0910–0471. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRASStaff@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.

Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun))

OMB Control Number 0910–0471—Extension

Section 519 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i) authorizes FDA to require: (1) manufacturers to report medical device-related deaths, serious injuries, and malfunctions and (2) user facilities to report device-related deaths directly to manufacturers and FDA and serious injuries to the manufacturer. Section 213 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 519(b) of the FD&C Act relating to mandatory reporting by user facilities of deaths, serious injuries, and serious illnesses associated with the use of medical devices. This amendment legislated the replacement of universal user facility reporting by a system that is limited to a “. . . subset of user facilities that constitutes a representative profile of user reports” for device-related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the FD&C Act (21 U.S.C. 360i(b)(5)(A)). This legislation provides FDA with the opportunity to design and implement a national surveillance network, composed of well-trained clinical facilities, to provide high-quality data on medical devices in clinical use. This system is called MedSun. FDA is seeking OMB clearance to continue to use electronic data collection to obtain information related to medical devices and tissue products from the user facilities participating in MedSun, to obtain a demographic profile of the facilities, and for additional questions, which will permit FDA to better understand the cause of reported adverse events. Participation in

the program is voluntary and includes approximately 300 facilities. In addition to collecting data on the electronic adverse event report form, MedSun collects additional information from participating sites about reported problems emerging from the MedSun hospitals. This data collection is also voluntary and is collected on the same website as the report information. The burden estimate is based on the number of facilities participating in MedSun (300). FDA estimates an average of 18 reports per site annually. This estimate is based on MedSun working to promote reporting in general from the sites, as well as promoting reporting from specific parts of the hospitals, such as the pediatric intensive care units, the electrophysiology laboratories, and the hospital laboratories.

In the **Federal Register** of July 17, 2026 (91 FR 44863), FDA published a 60-day notice soliciting public comment on the proposed extension of OMB Control Number 0910–0471. FDA received one comment, submitted by an

individual quality engineer with professional experience in medical device manufacturing, adverse event investigation, and CAPA program management. The commenter expressed support for the extension of the MedSun collection and offered suggestions in response to each of the four questions posed in the notice.

With respect to cost and hour burden, the commenter questioned the accuracy of the 30-minute-per-response estimate, noting that complex reports—particularly those involving serious injury, death, or multiple interacting devices—likely require significantly more time, especially in the specialty clinical environments FDA is actively recruiting (e.g., pediatric ICUs, electrophysiology labs). The commenter recommended that FDA validate the estimate against a stratified sample of actual reports broken out by complexity level, and that supplemental follow-up questions be counted as a separate burden line item, as they involve

additional staff time not captured in the initial submission estimate.

The current estimate of 0.5 hours per response reflects the average burden across all report types based on historical data and network feedback, and FDA considers it a reasonable approximation for PRA purposes. FDA will consider stratified burden estimation in the next renewal cycle.

The commenter also suggested several data quality and efficiency improvements—including adoption of IMDRF adverse event codes, UDI prompting with auto-population, a tiered short/long form structure, EHR integration via FHIR-based exchange, and the provision of aggregate feedback to participating sites. While these suggestions are outside the scope of the current PRA clearance, FDA will consider them in the context of ongoing MedSun program development and future collection instrument updates.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Adverse Event Reporting	300	18	5,400	.5 (30 minutes)	2,700

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–10605]

Agency Information Collection Activities; Proposed Collection; Comment Request; Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA’s guidance for industry entitled “Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations.”

DATES: Either electronic or written comments on the collection of information must be submitted by December 7, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 7, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such