

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.

[FR Doc. 2026–20661 Filed 10–7–26; 8:45 am]

BILLING CODE 4164–01–P

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

as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2026-N-10605 for “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.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management

Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:

Christopher Colburn, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8758, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the

validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

OMB Control Number 0910-0562—Extension

This information collection supports FDA guidance. The Food Quality Protection Act of 1996 (Pub. L. 104-170), which amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (Pub. L. 80-104) and the Federal Food, Drug, and Cosmetic Act (FD&C Act), established a new safety standard for pesticide residues in food, with an emphasis on protecting the health of infants and children. The Environmental Protection Agency (EPA) is responsible for regulating the use of pesticides (under FIFRA) and for establishing tolerances or exemptions from the requirement for tolerances for residues of pesticide chemicals in food commodities (under the FD&C Act). EPA may, for various reasons, *e.g.*, as part of a systematic review or in response to new information concerning the safety of a specific pesticide, reassess whether a tolerance for a pesticide residue continues to meet the safety standard in section 408 of the FD&C Act (21 U.S.C. 346a). When EPA determines that a pesticide’s tolerance level does not meet that safety standard, the registration for the pesticide may be canceled under FIFRA for all or certain uses. In addition, the tolerances for that pesticide may be lowered or revoked for the corresponding food commodities.

Under section 408(l)(2) of the FD&C Act, when the registration for a pesticide is canceled or modified due to, in whole or in part, dietary risks to humans posed by residues of that pesticide chemical on food, the effective date for the revocation of such tolerance (or exemption in some cases) must be no later than 180 days after the date such cancellation becomes effective or 180 days after the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

When EPA takes such actions, food derived from a commodity that was lawfully treated with the pesticide may not have cleared the channels of trade by the time the revocation or new tolerance level takes effect. The food could be found by FDA, the Agency that is responsible for monitoring pesticide residue levels and enforcing the pesticide tolerances in most foods (the U.S. Department of Agriculture has responsibility for monitoring residue levels and enforcing pesticide tolerances in meat, poultry, catfish, and certain egg products), to contain a residue of that pesticide that does not comply with the revoked or lowered tolerance. We would normally deem such food to be in violation of the law by virtue of it bearing an illegal pesticide residue. The food would be subject to FDA enforcement action as an “adulterated” food. However, the channels of trade provision of the FD&C Act addresses the circumstances under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical for which the tolerance has been revoked, suspended, or modified by EPA. The channels of trade provision (section 408(l)(5) of the FD&C Act) states that food containing a residue of such a pesticide shall not be deemed “adulterated” by virtue of the residue, if the residue is within the former tolerance, and the responsible party can demonstrate to FDA’s satisfaction that the residue is present as the result of an application of the pesticide at a time

and in a manner that were lawful under FIFRA.

To assist respondents with the information collection, we have developed the guidance document 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” (May 2005). The guidance represents FDA’s current thinking on its planned enforcement approach to the channels of trade provision of the FD&C Act and how that provision relates to FDA-regulated products with residues of pesticide chemicals for which tolerances have been revoked, suspended, or modified by EPA under dietary risk considerations. The guidance can be found at the following link: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-channels-trade-policy-commodities-residues-pesticide-chemicals-which-tolerances>.

We anticipate that food bearing lawfully applied residues of pesticide chemicals that are the subject of future EPA action to revoke, suspend, or modify their tolerances, will remain in the channels of trade after the applicable tolerance is revoked, suspended, or modified. If we encounter food bearing a residue of a pesticide chemical for which the tolerance has been revoked, suspended, or modified, we intend to address the situation in accordance with provisions of the

guidance. In general, we anticipate that the party responsible for food found to contain pesticide chemical residues (within the former tolerance) after the tolerance for the pesticide chemical has been revoked, suspended, or modified will be able to demonstrate that such food was handled, *e.g.*, packed or processed, during the acceptable timeframes cited in the guidance by providing appropriate documentation to FDA as discussed in the guidance document. We are not suggesting that firms maintain an inflexible set of documents where anything less or different would likely be considered unacceptable. Rather, we are leaving it to each firm’s discretion to maintain appropriate documentation to demonstrate that the food was so handled during the acceptable timeframes. Examples of documentation that we anticipate will serve this purpose consist of documentation associated with packing codes, batch records, and inventory records. These are types of documents that many food processors routinely generate as part of their basic food-production operations.

Description of Respondents: The likely respondents to this collection of information are firms in the produce and food processing industries that handle food products that may contain residues of pesticide chemicals after the tolerances for the pesticide chemicals have been revoked, suspended, or modified.

We estimate 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
Submission of documentation	1	1	1	3	3

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

We expect the total number of pesticide tolerances that are revoked, suspended, or modified by EPA under dietary risk considerations in the next 3 years to remain at a low level, as there

have been no changes to the safety standard for pesticide residues in food since 1996. Thus, we expect the number of submissions we receive under the guidance document to also remain at a

low level. However, to avoid counting this burden as zero, we have estimated the burden at one respondent making one submission a year for a total of one annual submission.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record	Total hours
Develop documentation process	1	1	1	16	16

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.

[FR Doc. 2026–20663 Filed 10–7–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Sickle Cell Disease Advisory Committee.

This will be a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Sickle Cell Disease Advisory Committee.

Date: November 16, 2026.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: Imaging and Clinical Impact on the Eye and Brain in Sickle Cell Disease.

Address: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20892.

Meeting Link: <https://videocast.nih.gov/watch/d8f60236-bb52-11f1-82c0-124f0a52e769>.

Meeting Format: Virtual Meeting.

Contact Person: Julie A. Panepinto, MD, MSPH, DFO/Executive Secretary SCDAC, Division of Blood Diseases and Resources, 31 Center Lane, Bethesda, MD 20892, (301) 435–0080, julie.panepinto@nih.gov.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes.

Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: www.nhlbi.nih.gov/meetings/index.htm, where an agenda and any additional information for the meeting will be posted when available.

Dated: October 5, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–20617 Filed 10–7–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Advisory Council on Parkinson's Research, Care, and Services (ACPRCS).

This is the third meeting of the ACPRCS, which was established by the Dr. Emmanuel Bilirakis and Honorable Jennifer Wexton National Plan to End Parkinson's Act of 2024 (Pub. L. 118–66). The Advisory Council is charged with providing advice to the Secretary of Health and Human Services (HHS) on Parkinson's-related issues. The meeting will focus on public-private partnerships (PPPs) that are working across the translational science spectrum to advance PDRD treatments and diagnostics.

The meeting is hybrid with options for in-person and virtual attendance—registration is required (see instructions below). Additionally, any member of the public can view the meeting via HHS Live Streaming: www.hhs.gov/live.

Name of Committee: Advisory Council on Parkinson's Research, Care, and Services (ACPRCS).

Date: November 9, 2026.

Time: 9:00 a.m. to 5:30 p.m.

Agenda: Presentations on public private partnerships focused on Parkinson's and related disorders; structured time for public comment; and discussion of next steps in developing recommendations for PDRD priorities.

Address: Hubert H. Humphrey Building, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201.

Meeting Format: In Person and Virtual Meeting.

Cost: The meeting is free and open to the public.

Deadlines:

• Register by 11:59 p.m. ET, Friday, October 23rd.

• *Public Comment Due Date:* October 26th by 5:00 p.m. ET.

Contact Person: Jordan Gladman, Deputy Executive Officer, National Institute of Neurological Disorders and Stroke, Bethesda, MD 20892, nationalPDplan@nih.gov.

Public Attendance: Seating is limited. Names need to be put on a list of expected attendees and forwarded to the security officers at HHS. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to federal buildings may change without notice. In the interest of security, NIH has procedures at <https://www.nih.gov/about-nih/visitor-information/campus-access-security> for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Please note that individuals entering HHS owned, leased, or operated facilities must present a REAL ID compliant credential or another federally approved form of identification. Below is the list of acceptable forms of ID.

- State-issued Enhanced Driver's License
- U.S. passport
- U.S. passport card
- DHS trusted traveler cards (Global Entry, NEXUS, SENTRI, FAST)
- U.S. Department of Defense ID, including IDs issued to dependents
- Permanent resident card
- Border crossing card
- An acceptable photo ID issued by a federally recognized Tribal Nation/Indian Tribe, including Enhanced Tribal Cards (ETCs)
- HSPD–12 PIV card
- Foreign government-issued passport
- Canadian provincial driver's license or Indian and Northern Affairs Canada card
- Transportation worker identification credential
- U.S. Citizenship and Immigration Services Employment Authorization Card (I–766)
- U.S. Merchant Mariner Credential
- Veteran Health Identification Card (VHIC)

Meeting Registration: Registration is open to all members of the public.