TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1.282 and 1.283(a)(5)	3540	64,621	1	64,621	0.25 (15 minutes)	16,155
Subtotal						23,072
Requests for Review and Post-hold Submissions:						
1.283(d) and 1.285(j)	N/A	1	0	1	8	8
1.285(i)	N/A	189	1	189	1	189
Subtotal						189
Mail Service and Tracking Number:						
One-Time Burden		5,460	1	5,460	0.50 (30 minutes)	2,730
Recurring Burden			143	780,780	0.07 (4 minutes)	54,655
Subtotal						57,385
Overall Total		331,765		25,761,671		5,419,656

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The term "Form FDA 3540" refers to the electronic submission system known as PNSI, which is available at *https://www.access.fda.gov.*

Since the last OMB approval, FDA has revised this information collection to consolidate the previously approved information collection under OMB Control No. 0910–0923, which covers the reporting requirements for the mail service and mail tracking number associated with prior notice submissions for articles of food arriving by international mail. Our estimated burden for this information collection reflects an overall increase of 7,629,528 hours and a corresponding increase of 1,721,959 responses. We attribute this adjustment to the overall growth in United States food importation, changes in *de minimis* exemptions, and the aforementioned new requirements for international mail shipments.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19281 Filed 9–18–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–10363]

Agency Information Collection Activities; Proposed Collection; Comment Request; Temporary Marketing Permit Applications

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 reporting requirements contained in existing FDA regulations governing temporary marketing permit applications.

DATES: Either electronic or written comments on the collection of information must be submitted by November 20, 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 November 20, 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–10363 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Temporary Marketing Permit

Applications.'' 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.

Temporary Marketing Permit Applications—21 CFR 21 CFR 130.17(c) and (i)

OMB Control Number 0910–0133—Extension

This information collection request supports FDA regulations found in 21 CFR 130.17. Section 401 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 341) directs FDA to issue regulations establishing definitions and standards of identity (SOIs) for food. Under section 403(g) of the FD&C Act (21 U.S.C. 343(g)), a food that is subject to a definition and SOI prescribed by regulation is misbranded if it does not conform to such definition and SOI. Section 130.17 provides for the issuance by FDA of temporary marketing permits (TMPs) that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions and SOIs. Section 130.17(c) enables the Agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable definitions and SOIs. The information obtained can be used in support of a petition to establish or amend the applicable definition or SOI to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a TMP. To assist respondents with the TMP process, we have developed guidance entitled ''Temporary Permits for Interstate Shipment of Experimental Packs of Food Varying from the Requirements of Definitions and Standards of Identity: Guidance for Industry'' (November 2021). This resource can be found on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-temporary-permits-interstate-shipment-experimental-packs-food-varying-requirements.*

Description of Respondents: Respondents to this collection of information include private sector businesses including institutional and/or industrial customers and food industry members such as manufacturers, packers, or distributors desiring to apply for a TMP or TMP extension.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
130.17(c); Request for TMP	13	2	26	25	650
130.17(i); Request for TMP extension	1	2	2	2	4

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total	654				

[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. 2026–19283 Filed 9–18–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Funding, Medicare Rural Hospital Flexibility Program Evaluation Cooperative Agreement

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental funding.

SUMMARY: HRSA is awarding supplemental funding under the Medicare Rural Hospital Flexibility (Flex) Program Evaluation Cooperative Agreement to one award recipient in fiscal year 2026 to expand analysis, evaluation, and dissemination activities that support Critical Access Hospitals (CAHs) and State Flex Programs.

FOR FURTHER INFORMATION CONTACT: Sheena Johnson, Deputy Division Director, Hospital State Division, Federal Office of Rural Health Policy, HRSA, at *sjohnson@hrsa.gov* and 872–271–6370.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Regents of the University of Minnesota.

Amount of Non-Competitive Award: $420,000.

Project Period: July 1, 2026, to June 30, 2027.

Assistance Listing Number: 93.241.

Award Instrument: Cooperative Agreement.

Authority: Section 711(b)(5) of the Social Security Act.

TABLE 1—RECIPIENT AND AWARD AMOUNT

Grant No.	Award recipient name	City, state	Award amount
U27RH01080	Regents of the University of Minnesota	Minneapolis, MN	$420,000

Justification: The FLEX Program Evaluation Cooperative Agreement supports rural health care improvement by analyzing and presenting CAH data, capturing best practices, and developing resources that inform quality, financial, operational, population health, and emergency medical services improvement efforts. This funding will provide a one-time supplement to the Regents of the University of Minnesota to expand analytic, evaluation, dissemination, and technical assistance support for CAHs and State Flex Programs. The recipient will use supplemental funding to conduct additional analysis using new Flex Program data, feedback on the annual CAH assessment, strengthen dissemination activities and accessibility to products and resources, and develop new resources to help inform tribal hospitals on feasibility of converting to another hospital provider type (*e.g.,* CAH).

Thomas J. Engels,

Administrator.

[FR Doc. 2026–19234 Filed 9–18–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Funding, State Offices of Rural Health Coordination and Development Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental funding.

SUMMARY: HRSA is awarding supplemental funding under the State Offices of Rural Health (SORH) Coordination and Development Program to one award recipient in fiscal year 2026 to support expanded technical assistance, capacity-building, and coordination activities for SORH and rural stakeholders nationwide.

FOR FURTHER INFORMATION CONTACT: Sheena Johnson, Deputy Division Director, Hospital State Division, Federal Office of Rural Health Policy, HRSA, at *sjohnson@hrsa.gov* and 872–271–6370.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: National Organization of State Offices of Rural Health, Inc.

Amount of Non-Competitive Award: $345,000.

Project Period: August 1, 2026, to July 31, 2027.

Assistance Listing Number: 93.913.

Award Instrument: Cooperative Agreement.

Authority: Section 711(b) of the Social Security Act.