III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: November 19, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–28033 Filed 11–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4687]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medicated Feed Mill License Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 medicated feed mill license reporting.

DATES: Either electronic or written comments on the collection of information must be submitted by January 28, 2025.

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 January 28, 2025. 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–2024–N–4687 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Medicated Feed Mill License Application.'' 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: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Medicated Feed Mill License Application—21 CFR Part 515

OMB Control Number 0910–0337—Extension

This information collection helps support implementation of statutory and regulatory provisions related to medicated animal feed mill licensing. Feed manufacturers that seek to manufacture a Type B or Type C medicated feed using Category II, Type A medicated articles or manufacture certain liquid and free-choice feed using Category I, Type A medicated articles that must follow proprietary formulas or specifications, are required to obtain a facility license under section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b). Our regulations in 21 CFR part 515 establish the procedures associated with applying for a facility license. We require that a manufacturer seeking a facility license submit a completed medicated feed mill license application using Form FDA 3448 (21 CFR 515.10(b)). This form may be submitted via U.S. mail or electronically to a dedicated email address, *MedicatedFeedsTeamMail@fda.hhs.gov.* We use the information submitted to establish that the applicant has made the certifications required by section 512 of the FD&C Act, to register the mill, and to schedule a preapproval inspection. Form FDA 3448 may be accessed on our website at: *https://www.fda.gov/about-fda/reports-manuals-forms/forms.*

We require the submission of a supplemental medicated feed mill license application for a change in facility ownership or a change in facility address (§ 515.11(b) (21 CFR 515.11(b))). If a licensed facility is no longer manufacturing medicated animal feed under § 515.23 (21 CFR 515.23), a manufacturer may request voluntary revocation of a medicated feed mill license. An applicant also has the right to file a request for hearing under § 515.30(c) (21 CFR 515.30(c)) to give reasons why a medicated feed mill license should not be refused or revoked.

Under § 510.305 (21 CFR 510.305), we require each applicant to maintain in a single accessible location: (a) A copy of the approved medicated feed mill license (Form FDA 3448) on the premises of the manufacturing establishment; and (b) approved or index listed labeling for each Type B and/or Type C feed being manufactured on the premises of the manufacturing establishment or the facility where the feed labels are generated.

FDA estimates 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
515.10(b), 515.11(b); Medicated Feed Mill License Application and Supplemental Applications using Form FDA 3448	34	1	34	0.25 (15 minutes)	8.5
515.23; Voluntary Revocation of Medicated Feed Mill License	14	1	14	0.25 (15 minutes)	3.5
515.30; Filing a Request for a Hearing on Medicated Feed Mill License	1	1	1	4	4
Total			49		16

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

We estimate that respondents will spend 15 minutes to assemble the necessary information, prepare, and submit an application for a feed mill license or revocation of a feed mill license. We estimate that respondents will spend 4 hours to prepare their request for a hearing.

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
510.305; Maintenance of Records for Approved Labeling for Each "Type B" and "Type C" Feed.	779	1	779	0.03 (2 minutes)	23

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

We base our estimates on our recent experience with the existing medicated feed mill license application process. Our estimated burden for the information collection reflects an overall increase of 2.5 hours. We

attribute this adjustment to a slight increase in the overall number of submissions we received over the last few years.

Dated: November 19, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–28036 Filed 11–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Final Health Center Program Policy Guidance Regarding Services To Support Transitions in Care for Justice-Involved Individuals Reentering the Community

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

ACTION: Final notice.

SUMMARY: The final Health Center Program Policy Guidance Regarding Services to Support Transitions in Care for Justice-Involved Individuals Reentering the Community Policy Information Notice (JI–R PIN) has been developed to assist health centers who choose to provide certain primary health care services to support the transition of JI–R individuals from the carceral setting back into the community setting.

DATES: This Final JI–R PIN is effective on the date of publication of this notice.

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, use the HRSA Bureau of Primary Health Care Contact Form: *https://hrsa.force.com/support/s/* or call Jennifer Joseph, Director, Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, at 301–594–4300.

SUPPLEMENTARY INFORMATION: HRSA provides grants to eligible applicants under section 330 of the Public Health Service Act, as amended (42 U.S.C. 254b), to support the delivery of preventive and primary care services to the nation's underserved individuals and families. HRSA also certifies eligible applicants under the Health Center Look-Alike Program (see sections 1861(aa)(4)(B) and 1905(l)(2)(B) of the Social Security Act). Look-alikes do not receive Health Center Program funding but must meet the Health Center Program statutory and regulatory requirements. Health centers are local organizations that provide comprehensive, high-quality primary health care services tailored to their communities regardless of their patients' ability to pay. Nearly 1,400 Health Center Program-funded health centers and more than 100 Health Center Program look-alike organizations operate more than 16,100 service delivery sites that provide care to more than 32 million patients in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. Note that for the purposes of this document, the term ''health center'' refers to entities that receive a federal award under section 330 of the Public Health Service Act, as well as subrecipients and organizations designated as look-alikes, unless otherwise stated.

This final JI–R PIN establishes policy for all health centers that apply for and receive a federal award under the Health Center Program, as authorized by section 330 of the Public Health Service (PHS) Act (including sections 330(e), (g), (h), and (i)), as well as section 330 subrecipient organizations and Health Center Program look-alikes. This final JI–R PIN is intended to support health centers in providing certain health services—delivered under the exclusive control and authority of the health center—to support the transition of JI–R individuals from the carceral setting back into the community setting. The services the health center provides are limited to services that support reentry. A health center may not take on or replace the provision of any other health care services the carceral authority provides to those who are incarcerated or detained.

HRSA released a draft of the JI–R PIN for a 60-day public comment period. HRSA revised the JI–R PIN in response to comments and posted a summary of comments and HRSA's responses at *https://bphc.hrsa.gov/sites/default/files/bphc/compliance/pin-2024-05-comments-summary.pdf.*

Organizations receiving Health Center Program federal awards, including subrecipients, and organizations designated as Health Center Program look-alikes, continue to be subject to all requirements stated in Notices of Funding Opportunity, Notices of Award, Look-Alike Initial Designation and Redesignation Instructions, Notices of Look-Alike Designation, as well as other applicable laws, regulations, and policies. Organizations are also subject to the distinct statutory, regulatory, and policy requirements of other federal programs in which they participate.

Carole Johnson,

Administrator.

[FR Doc. 2024–27903 Filed 11–27–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2025, Through September 30, 2026

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: The Federal Medical Assistance Percentages (FMAP), Enhanced Federal Medical Assistance Percentages (eFMAP), and disaster-recovery FMAP adjustments for fiscal year 2026 have been calculated pursuant to the Social Security Act (the Act). These percentages will be effective from October 1, 2025, through September 30, 2026. This notice announces the calculated FMAP rates, in accordance with the Act, that the U.S. Department of Health and Human Services (HHS) will use in determining the amount of Federal matching for state medical assistance (Medicaid), Temporary Assistance for Needy Families (TANF) Contingency Funds, Child Support collections, Child Care Mandatory and Matching Funds of the Child Care and Development Fund, Title IV–E Foster Care Maintenance payments, Adoption Assistance payments and Kinship Guardianship Assistance payments, and the eFMAP rates for the Children's Health Insurance Program (CHIP) expenditures. Table 1 gives figures for each of the 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. This notice reminds states of adjustments available for states meeting requirements for disproportionate employer pension or insurance fund contributions and adjustments for disaster recovery. Based on the criteria for a qualifying state, one state meets the requirements for an adjustment for disaster recovery.

DATES: The percentages listed in Table 1 will be effective for each of the four quarter-year periods beginning October 1, 2025, and ending September 30, 2026.