

Country Bancshares, Inc. and indirectly retain voting shares of Llano National Bank, both of Llano, Texas.

Board of Governors of the Federal Reserve System.

**Michele Taylor Fennell,**

*Deputy Associate Secretary of the Board.*

[FR Doc. 2024-02807 Filed 2-9-24; 8:45 am]

**BILLING CODE P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for Office of Management and Budget (OMB) Review; State Personal Responsibility Education Program (PREP) (OMB #0970-0380)**

**AGENCY:** Family and Youth Services Bureau, Administration for Children and Families, U.S. Department of Health and Human Services.

**ACTION:** Request for public comments.

**SUMMARY:** The Family and Youth Services Bureau (FYSB) within the Administration on Children, Youth and Families (ACYF) is requesting a 3-year extension of the State Personal Responsibility Program (PREP) state plans and performance progress report (OMB #0970-0380, expiration 12/31/2023). There are no changes requested to the state plan, but there are changes requested to the performance progress report. Changes include the addition of

information related to equity activities and strategies to mitigate challenges.

**DATES:** *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. You can also obtain copies of the proposed collection of information by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Identify all emailed requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* The State PREP has mandatory, formula allotments for state and territories to apply. The process is for states and territories to submit and for ACYF/FYSB to collect their state plans and semi-annual performance progress reports.

*Purpose and Use of the Information Collection:* The state plan offers information about the proposed state project and has been and will continue to be used as the primary basis to

determine whether or not the project meets the minimum requirements of the legislation for the grant award. There are no changes proposed to the state plan; FYSB is requesting to use these plans for another 3 years.

The Performance Progress Reports are collected semi-annually and inform the monitoring of the grantees’ program design, program evaluation, management improvement, service quality, and compliance with agreed upon goals. ACYF/FYSB has used and will continue to use the information to ensure effective service delivery for program participants. Finally, the data from this collection will be used to report outcomes and efficiencies and will provide valuable information to policy makers and key stakeholders in the development of program and research efforts. Changes are proposed to the Performance Progress Reports and include the addition of information related to equity activities and strategies to mitigate challenges. Information on equity activities will be used to support the FYSB Equity Action Plan objectives and to inform the development of T&TA resources, as needed. The purpose of including strategies to mitigate challenges is to allow grant recipients to demonstrate how they overcome challenges. This information can be used to inform peer to peer sharing.

*Respondents:* All 52 states and territories that are still eligible to accept their State PREP mandatory, formula allotments for funding.

**ANNUAL BURDEN ESTIMATES**

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
State Plans .....	52	1	40	2,080
Performance Progress Reports .....	52	2	16	1,664

*Estimated Total Annual Burden Hours:* 3,744.

*Authority:* Section 513 of the Social Security Act (42 U.S.C. 713), as amended by section 50503 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123) extended by Division CC, Title III, Section 302 of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260).

**Mary C. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2024-02749 Filed 2-9-24; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2023-D-5303]**

**Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination and Removal of a Foreign Manufacturer’s Goods From Detention Without Physical Examination; Draft Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled “Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination (DWPE) and Removal of a Foreign Manufacturer’s Goods from DWPE.” The draft guidance, when finalized, will provide recommendations for collecting a representative sample for products subject to DWPE under an import alert

due to the appearance of adulteration caused by pathogens, unlawful animal drugs, scombrototoxin (histamine), and/or decomposition. When finalized, the draft guidance will also help foreign manufacturers and other processors of fish and fishery products subject to DWPE introduce evidence to FDA to support a request to have products removed from DWPE.

**DATES:** Submit either electronic or written comments on the draft guidance by April 12, 2024 to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *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-

2023-D-5303 for "Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination (DWPE) and Removal of a Foreign Manufacturer's Goods from DWPE; Draft Guidance for Industry." Received comments 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." We will review this copy, including the claimed confidential information, in our 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Seafood Safety, Office of

Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

#### **FOR FURTHER INFORMATION CONTACT:**

Steven Bloodgood, Office of Food Safety (HFS-325), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-5316; or Holli Kubicki, Office of Regulations and Policy (HFS-024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

We are announcing the availability of a draft guidance for industry entitled "Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination (DWPE) and Removal of a Foreign Manufacturer's Goods from DWPE." We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

Under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(a)(3)), an article of food imported or offered for import into the United States is subject to refusal of admission if it appears "from the examination of such samples or otherwise" to be adulterated. FDA issues import alerts to inform its field staff about products that appear to be in violation of FDA's laws and regulations and thus may be detained without physical examination. We may subject future shipments of fish or fishery products to DWPE when there is information that causes future shipments of a product or products to appear violative within the meaning of section 801(a) of the FD&C Act. Such information may exist based on the violative history of a product, manufacturer, shipper, grower, importer, geographic area, or country.

To carry out the provisions of section 801(a) of the FD&C Act when we detain

an article that appears violative, we provide notice to the owner or consignee of the nature of the violation and the right to present testimony regarding the admissibility of the article (21 CFR 1.94). Frequently, owners or consignees submit analytical test results based on samples taken from the article subject to DWPE as evidence demonstrating admissibility. We then determine if the testimony (analytical package, information, or other evidence) is sufficient. If the evidence is adequate to overcome the appearance of the violation(s), FDA will allow the article to proceed for entry into the United States. If the evidence is not adequate to remove the appearance of the violation(s), the entry will be refused admission into the United States.

In addition, interested parties may request that their products be removed from DWPE. FDA decisions to remove a product, manufacturer, or other entity from DWPE are based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and we have confidence that future shipments of the product to the United States will be in compliance with the FD&C Act. FDA may consider analytical results from successful consecutive tests as part of the evidence to support removal from DWPE.

The draft guidance, when finalized, will provide recommendations for collecting a representative sample for products subject to DWPE under an import alert due to the appearance of adulteration caused by pathogens, unlawful animal drugs, scombrotoxin (histamine), and/or decomposition. When finalized, the draft guidance will also help foreign manufacturers and other processors of fish and fishery products subject to DWPE introduce evidence to FDA to support a request to have products removed from DWPE.

The recommendations in the draft guidance include sample sizes based on a critical nonconformities sampling strategy. Using this statistical sampling equation, the amount of sampling recommended can be structured commensurate with the level of concern, and risk to consumers, associated with the type of adulteration to be addressed. For more information, see “Derivation of Sampling Recommendations Related to Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination (DWPE) and Removal of a Foreign Manufacturer’s Goods from DWPE; Guidance for Industry” (Ref. 1).

As the draft guidance makes clear, persons may propose alternative sampling plans and explain the basis for such alternatives.

We note that the draft guidance refers to the final rule entitled “Laboratory Accreditation for Analyses of Foods” (LAAF Rule, which is codified at 21 CFR part 1, subpart R). FDA is taking a stepwise approach to implementing the LAAF Rule based, in part, on reaching sufficient LAAF-accredited laboratory capacity for food testing (see 86 FR 68728 at 68739 and 68740, December 3, 2021). FDA may publish one or more documents in the **Federal Register** giving owners and consignees 6 months’ notice before requiring them to use a LAAF-accredited laboratory for food testing covered by the rule (id.). We will monitor LAAF Rule implementation and update any final guidance based on this draft guidance accordingly.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 1, subpart R have been approved under OMB control number 0910–0898.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/FoodGuidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

## IV. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>.

1. FDA, “Derivation of Sampling Recommendations Related to Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination (DWPE) and Removal of a Foreign Manufacturer’s Goods from DWPE; Guidance for Industry.”

Dated: February 7, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2023–D–4974]

#### **Advanced Manufacturing Technologies Designation Program; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Extension of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability entitled “Advanced Manufacturing Technologies Designation Program; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request” that appeared in the **Federal Register** of December 13, 2023. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the document published on December 13, 2023 (88 FR 86333). Either electronic or written comments must be submitted by March 13, 2024.

**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 March 13, 2024. 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