inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 2, 2013.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Heartland Financial USA, Inc.,* Dubuque, Iowa, to acquire 100 percent of Morrill Bancshares, Inc., Merriam, Kansas, and thereby indirectly acquire, The Morrill & Janes Bank and Trust Company, Overland Park, Kansas.

B. Federal Reserve Bank of St. Louis (Yvonne Sparks, Community Development Officer) P.O. Box 442, St. Louis, Missouri 63166–2034:

1. *Home Bancshares, Inc.,* Conway, Arkansas, to merge with Liberty Bancshares, Inc. and thereby indirectly acquire Liberty Bank of Arkansas, both of Jonesboro, Arkansas.

C. Federal Reserve Bank of Minneapolis (Jacqueline G. King, Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Tolna Bancorp, Inc.,* Tolna, North Dakota, to acquire 100 percent of McVille Financial Services, Inc., McVille, North Dakota, and thereby indirectly acquire McVille State Bank, McVille, North Dakota. Comments must be received by July 29, 2013.

Board of Governors of the Federal Reserve System, July 3, 2013.

Michael Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2013–16417 Filed 7–8–13; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: OCSE–75 Tribal Child Support Enforcement Program Annual Data Report.

OMB No.: 0970–0320

Description: The data collected by form OCSE–75 are used to prepare the OCSE preliminary and annual data reports. In addition, Tribes administering CSE programs under Title IV–D of the Social Security Act are required to report program status and accomplishments in an annual narrative report and submit the OCSE–75 report annually.

Respondents: Tribal Child Support Enforcement Organizations or the Department/Agency/Bureau responsible for Child Support Enforcement in each tribe.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE–75	60	1	60	3,600

Estimated Total Annual Burden Hours: 3,600.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning 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. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–16357 Filed 7–8–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0319]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information

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: Fax written comments on the collection of information by August 8, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Draft Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–

400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@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.

Draft Guidance for Industry on and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information—(OMB Control Number 0910–New)

This draft guidance provides recommendations on when to use a Dear Health Care Provider (DHCP) Letter, the types of information to include in a DHCP letter, how to organize that information, and formatting techniques to make the information more accessible. The draft guidance is intended to improve the quality of DHCP letters to make them more effective communication tools for new information about marketed products.

In the **Federal Register** of November 12, 2010 (75 FR 69449), FDA published a 60-day notice requesting public comment on the draft version of this guidance. Eleven public comments were received during the comment period and in nine of the letters the following two issues were raised. However, the other two comments did not address the information collection.

(Comment 1) Section V of the draft guidance states that the target audience should be all health care providers who could not only prescribe the drug, but who could also dispense or administer the drugs. The comments call this an expansion of the target audience, which would require manufacturers to send DHCP letters to physicians, nurses, pharmacists, and other prescribing and non-prescribing providers. Manufacturers would also need to seek out lists of such non-prescribing health care providers proactively and disseminate the letters more broadly than to just physicians. A recommendation was made to limit the letters to prescribers only.

(Response) The regulation requires manufacturers and distributors to mail important information to ''physicians and others responsible for patient care''. (See 21 CFR 200.5) To the extent this includes non-prescribing health care professionals responsible for patient care, the manufacturers should send letters to relevant personnel. This is not an expansion of the scope of the letters, merely a clarification of the regulation and a reflection of the health care system today, which has a variety of practitioners involved in patient care.

(Comment 2) In Section VI of the draft guidance, FDA recommends that companies conduct an evaluation of the extent to which the target audience received the DHCP letter and is aware of the information that was communicated in the letter. It also asked manufacturers to assess the impact of DHCP letters and their impact on patient behavior. Comments found this overly burdensome, beyond the Agency's statutory authority, and an unnecessary increase in correspondence, thereby potentially diluting the impact of the DHCP letters.

(Response) We agree with the comments. The final guidance has been modified to suggest that manufacturers conduct an evaluation, *for their own use,* of the utility of the letters and their success in reaching the target audiences.

Based on a review of MedWatch Safety Alerts for 2008 and 2009, we identified each Dear Health Care Provider Letter sent and the identity of each sponsor sending out a Dear Health Care Provider Letter for each year. We estimate that we will receive approximately 30 Dear Health Care Provider Letters annually from approximately 25 application holders. FDA professionals familiar with Dear Health Care Provider Letters and with the recommendations in the draft guidance estimate that it should take an application holder approximately 100 hours to prepare and send Dear Health Care Provider Letters in accordance with the draft guidance. Therefore we estimate the annual reporting burden as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual Average	25	1.20	30	100	3,000

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

In the draft guidance, we refer to an earlier guidance for industry entitled ''Using Electronic Means to Distribute Certain Product Information'' (71 FR 26102; May 3, 2006). That guidance referred to previously approved collections of information found in FDA regulations that are subject to review by OMB. The collections of information in that guidance have been approved under OMB control number 0910–0249.

Dated: July 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–16445 Filed 7–8–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0795]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Third-Party Review Under the Food and Drug Administration Modernization Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 associated with medical devices third-party review under the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit either electronic or written comments on the collection of information by September 9, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written