

**FEDERAL RESERVE SYSTEM****Formations of, Acquisitions by, and Mergers of Bank Holding Companies**

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate 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 July 31, 2014.

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

1. *First Light Bancorp*, Evansville, Indiana; to become a bank holding company by acquiring 100 percent of the voting shares of Evansville Commerce Bank, Evansville, Indiana.

Board of Governors of the Federal Reserve System, July 1, 2014.

**Michele Taylor Fennell**,

*Assistant Secretary of the Board.*

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**DEPARTMENT OF DEFENSE****GENERAL SERVICES ADMINISTRATION****NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**

[OMB Control No. 9000-0018; Docket 2014-0055; Sequence 8]

**Submission to OMB for Review; Federal Acquisition Regulation; Certification of Independent Price Determination and Parent Company and Identifying Data**

**AGENCY:** Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of request for public comments regarding an extension to an existing OMB clearance.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), the Regulatory Secretariat Division (MVCB) will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning certification of independent price determination and parent company and identifying data. A notice was published in the **Federal Register** on April 14, 2014. No comments were received.

**DATES:** Submit comments on or before August 6, 2014.

**ADDRESSES:** Submit comments identified by Information Collection 9000-0018, Certification of Independent Price Determination and Parent Company and Identifying Data by any of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching the OMB control number 9000-0018. Select the link "Comment Now" that corresponds with "Information Collection 9000-0018, Certification of Independent Price Determination and Parent Company and Identifying Data." Follow the instructions provided on the screen. Please include your name, company name (if any), and "Information Collection 9000-0018, Certification of Independent Price Determination and Parent Company and Identifying Data" on your attached document.

- *Fax:* 202-501-4067.

- *Mail:* General Services

Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000-0018.

*Instructions:* Please submit comments only and cite Information Collection 9000-0018, in all correspondence related to this collection. All comments received will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided.

**FOR FURTHER INFORMATION CONTACT:** Mr. Edward Chambers, Procurement Analyst, Federal Acquisition Policy Division, GSA 202-501-3221 or [Edward.chambers@gsa.gov](mailto:Edward.chambers@gsa.gov).

**SUPPLEMENTARY INFORMATION:****A. Purpose**

As a first step in assuring that Government contracts are not awarded to firms violating anti-trust laws, offerors on Government contracts must complete the certificate of independent price determination. The Contracting Officer will reject certificates where the offeror has deleted or modified portions of the certificate and has not furnished with the certificate a signed statement of the circumstances of disclosure of prices. Agencies are required to report to the Attorney General rejected offers where the offeror deleted or modified the certificate or the certificate is suspected of being false.

The information collection is required each time an offeror responds to a solicitation for firm-fixed price contract or fixed-price economic price adjustment contract unless the acquisition is: (1) Made under the simplified acquisition threshold; (2) at the request for technical proposals under two-step sealed bidding procedures; or (3) for utility services for which rates are set by law or regulation. The FAR rule requires a Certificate of Independent Price Determination so that contractors certify that the prices in their offer have been arrived at independently, have not been or will not be knowingly disclosed, and have not been submitted for the purpose of restricting competition. This clause does not apply to commercial items.

**B. Annual Reporting Burden**

A reassessment of FAR 3.103 and FAR 52.203-2 was performed. Based on the comprehensive reassessment performed, this information collection resulted in a slight decrease in the annual number of responses and an increase in the annual time burden from the previous information collection that was published in the **Federal Register** at 76 FR 37353 on June 27, 2011. The decrease in the annual number of responses was likely a result of updated Fiscal Year 2013 data obtained from the Federal Procurement Data System. The

increase in the annual time burden resulted from increases in the amount of time necessary to research and prepares the certification from .01 hours (less than one minute) to .25 hours (15 minutes). No public comments were received in prior years that have challenged the validity of the Government's estimate.

*Respondents:* 13,486.

*Responses per Respondent:* 76.

*Total Responses:* 1,024,936.

*Hours per Response:* .25.

*Total Burden hours:* 256,234.

### C. Public Comments

*Public comments are particularly invited on:* Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

#### *Obtaining Copies of Proposals:*

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000-0018, telephone 202-501-4755.

Please cite OMB Control No. 9000-0018, Certification of Independent Price Determination and Parent Company and Identifying Data, in all correspondence.

Dated: June 27, 2014.

**Karlos Morgan,**

*Acting Director, Federal Acquisition Policy Division, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.*

[FR Doc. 2014-15639 Filed 7-3-14; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0085]

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics**

**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 proposed extension of the collection of information concerning cooperative manufacturing arrangements for licensed biologics.

**DATES:** Submit either electronic or written comments on the collection of information by September 5, 2014.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), 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.

#### **Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics—(OMB Control Number 0910-0629)—Extension**

The guidance document provides information concerning cooperative manufacturing arrangements applicable to biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262). The guidance addresses several types of manufacturing arrangements (i.e., short supply arrangements, divided manufacturing arrangements, shared manufacturing arrangements, and contract manufacturing arrangements) and describes certain reporting and recordkeeping responsibilities, associated with these arrangements, including the following: (1) Notification of all important proposed changes to production and facilities; (2) notification of results of tests and investigations regarding or possibly impacting the product; (3) notification of products manufactured in a contract facility; and (4) standard operating procedures.

#### **1. Notification of All Important Proposed Changes to Production and Facilities**

Each licensed manufacturer in a divided manufacturing arrangement or shared manufacturing arrangement must notify the appropriate FDA Center regarding proposed changes in the manufacture, testing, or specifications of its product, in accordance with § 601.12 (21 CFR 601.12). In the guidance, we recommend that each licensed manufacturer that proposes such a change should also inform other participating licensed manufacturer(s) of the proposed change.

For contract manufacturing arrangements, we recommend that the contract manufacturer should share with the license manufacturer all important proposed changes to production and facilities (including