

documents containing CBI, and bars public disclosure of any designated CBI by any party to the action except in accordance with the order. With limited exceptions, parties must destroy or return CBI received in discovery within 90 days of the end of the litigation.

Dated: October 2, 2019.

John Michaud,

Associate General Counsel.

[FR Doc. 2019-22209 Filed 10-9-19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2013-0437; FRL-10001-00-OAR]

Proposed Information Collection Request; Comment Request; Emission Control System Performance Warranty Regulations and Voluntary Aftermarket Part Certification Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), "Emission Control System Performance Warranty Regulations and Voluntary Aftermarket Part Certification Program (Renewal)" (EPA ICR No. 0116.12, OMB Control No. 2060-0060) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through May 30, 2020. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before December 9, 2019.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA-HQ-OAR-2013-0437, online using www.regulations.gov (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential

Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Lynn Sohacki, Compliance Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 2000 Traverwood, Ann Arbor, Michigan 48105; telephone number: 734-214-4851; fax number 734-214-4869; email address: sohacki.lynn@epa.gov.

SUPPLEMENTARY INFORMATION:

Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: Under section 206(a) of the Clean Air Act (42 U.S.C. 7521), on-highway engine and vehicle manufacturers may not legally introduce their products into US commerce unless EPA has certified that their production complies with applicable emission standards. Per section 207(a), original vehicle manufacturers must warrant that vehicles are free from defects in materials and workmanship that would

cause the vehicle not to comply with emission regulations during its useful life. Section 207(a) directs EPA to provide certification to those manufacturers or builders of automotive aftermarket parts that demonstrate that the installation and use of their products will not cause failure of the engine or vehicle to comply with emission standards. An aftermarket part is any part offered for sale for installation in or on a motor vehicle after such vehicle has left the vehicle manufacturer's production line (40 CFR 85.2113(b)). Participation in the aftermarket certification program is voluntary. Aftermarket part manufacturers or builders (manufacturers) electing to participate conduct emission and durability testing as described in 40 CFR part 85, subpart V, and submit data about their products and testing procedures. Any information submitted to the Agency for which a claim of confidentiality is made is safeguarded according to policies set forth in CFR title 40, chapter 1, part 2, subpart B—Confidentiality of Business Information (see 40 CFR part 2).

Form numbers: None.

Respondents/affected entities:

Manufacturers or builders of automotive aftermarket parts.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 1 (total).

Frequency of response: On occasion.

Total estimated burden: 547 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$19,063 (per year), which includes \$1,955 annualized capital or operation & maintenance costs.

Changes in estimates: There is no change in the total estimated respondent burden compared with the ICR currently approved by OMB.

Dated: October 2, 2019.

Byron J. Bunker,

Director, Compliance Division, Office of Transportation and Air Quality, Office of Air and Radiation.

[FR Doc. 2019-22208 Filed 10-9-19; 8:45 am]

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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, if any, 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)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th and Constitution Avenue NW, Washington, DC 20551-0001, not later than November 12, 2019.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23219. Comments can also be sent electronically to or Comments.applications@rich.frb.org:

1. *First Community Bankshares, Inc., Bluefield, Virginia*; to acquire Highlands Bankshares, Inc., and thereby indirectly acquire Highlands Union Bank, both of Abingdon, Virginia.

Board of Governors of the Federal Reserve System, October 4, 2019.

Michele T. Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019-22154 Filed 10-9-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1788]

Intravascular Catheters, Wires, and Delivery Systems With Lubricious Coatings—Labeling Considerations; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings—Labeling

Considerations.” This guidance addresses labeling considerations for devices containing lubricious coatings used in the vasculature. The purpose of this guidance is to provide recommendations for information to be included in the device labeling, as submitted in premarket applications (PMAs) or premarket notification submissions (510(k)s) for Class III and Class II devices, to enhance the consistency of information across these product areas as well as to promote the safe use of these devices in the clinical setting.

DATES: The announcement of the guidance is published in the **Federal Register** on October 10, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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-2018-D-1788 for “Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings—Labeling Considerations.” 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.

- **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.gpo.gov/fdsys/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.

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for