

Additionally submit a copy to GSA 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 9000-0047. Select the link “Comment Now” that corresponds with “Information Collection 9000-0047, Place of Performance”. Follow the instructions provided on the screen. Please include your name, company name (if any), and “Information Collection 9000-0047 Place of Performance” on your attached document.

- *Mail*: General Services Administration, Regulatory Secretariat Division (MVCB) 1800 F Street NW, Washington, DC 20405. ATTN: Ms. Mandell/IC 9000-0047, Place of Performance.

Instructions: Please submit comments only and cite Information Collection 9000-0047 Place of Performance, 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. Michael O. Jackson, Procurement Analyst, Acquisition Policy Division at 202-208-4949 or email michaelo.jackson@gsa.gov.

A. Purpose

The information relative to the place of performance and owner of plant or facility, if other than the prospective contractor, is a basic requirement when contracting for supplies or services (including construction). A prospective contractor must affirmatively demonstrate its responsibility. Hence, the Government must be apprised of this information prior to award. The contracting officer must know the place of performance and the owner of the plant or facility to (1) determine bidder responsibility; (2) determine price reasonableness; (3) conduct plant or source inspections; and (4) determine whether the prospective contractor is a manufacturer or a regular dealer.

The information is used to determine the prospective contractor's eligibility for awards and to assure proper preparation of the contract. Prospective contractors are only required to submit place of performance information on an exceptional basis; that is, whenever the place of performance for a specific solicitation is different from the address of the prospective contractor as indicated in the proposal. A notice was published in the **Federal Register** at 82

FR 51257 on November 3, 2017. No comments were received.

B. Annual Reporting Burden

Time required to read, prepare, and record information is estimated at 2.73 minutes per completion. The Federal Procurement Data System (FPDS) shows that for fiscal year 2016, there were 1,960,218 solicitations that would have contained the two provisions (including contracts and orders, excluding modifications) for manufacturing in the United States. The 1,960,218 actions will be used as the new basis for total annual responses.

Respondents: 16,754.

Responses per Respondent: 117.

Total Responses: 1,960,218.

Hours per Response: .0455.

Total Burden Hours: 89,190.

Affected Public: Businesses or other for-profit and not-for-profit.

Respondent's Obligation: Required to obtain or retain benefits.

Type of Request: Revision of a currently approved collection.

Reporting Frequency: On occasion.

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, telephone 202-501-4755. Please cite OMB Control No. 9000-0047, Place of Performance, in all correspondence.

Dated: January 12, 2018.

Lorin S. Curit,

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

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000-0153; Docket 2017-0053; Sequence 17]

Submission for OMB Review; OMB Circular A-119

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

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, 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 previously approved information collection requirement concerning OMB Circular A-119.

DATES: Submit comments on or before February 20, 2018.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA 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 9000-0153. Select the link “Comment Now” that corresponds with “Information Collection 9000-0153, OMB Circular A-119”. Follow the instructions provided on the screen. Please include your name, company name (if any), and “Information Collection 9000-0153, OMB Circular A-119” on your attached document.

- *Mail*: General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. ATTN: Ms. Mandell/IC 9000-0153, OMB Circular A-119.

Instructions: Please submit comments only and cite Information Collection 9000-0153, OMB Circular A-119, 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. Michael O. Jackson, Procurement Analyst, Acquisition Policy Division, GSA 202-208-4949 or email michaelo.jackson@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

A revised OMB Circular A-119, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,” was published at https://www.nist.gov/sites/default/files/revise/circular_a-119_as_of_01-22-2016.pdf, on January 22, 2016. FAR Subparts 11.1 and 11.2 were revised and a solicitation provision was added at 52.211-7, Alternatives to Government-Unique Standards, to implement the requirements of the revised OMB

circular. If an alternative standard is proposed, the offeror must furnish data and/or information regarding the alternative in sufficient detail for the Government to determine if it meets the Government's requirements.

We believe the burden for FAR 52.211-7 to be negative, as it is purely a permissive means for offerors to propose reducing regulatory burden on a given solicitation. There are other places A-119 has an effect, though we believe these to be positive. One is by enabling the single process initiative. Another is the general replacement of Mil standards with commercial standards, e.g., ISO 9000. Also, A-119 is the basis for the language in FAR 53.105, which reduces the chaos in data standards development. The whole purpose of A-119 was to reduce regulatory burden by promoting the use of industry standards in lieu of federal ones.

To the extent that the data on the annual frequency of the use of voluntary consensus standards under FAR 52.211-7 is not available, we believe 100 is reasonable. As an aside, FAR part 45 recognizes the use of voluntary consensus standards in the management of Government property. However, in these cases, there is no Government standard per se, with the voluntary consensus standard serving as the Government standard. Consequently, when under part 45 voluntary consensus standards are used, they are not an alternative to a Government standard under FAR 52.211-7.

This collection implements OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards. FAR solicitation provision 52.211-7, Alternatives to Government-Unique Standards, is the collection instrument. We have previously indicated that "to the extent that the data on the annual frequency of the use of voluntary consensus standards under FAR 52.211-7 is not available, we believe that 100 is reasonable." This is the number that has been reported since the inception of this PRA collection, which indicates that revised data has been consistently unavailable since responses are provided to contracting personnel at the local level in response to a local solicitation. We checked the FPDS data dictionary and there are no codes to flag data fields or provide a count of when Mil standards are used in solicitations/contracts. Considering the lack of FPDS or other data, we recommend continuing the PRA coverage at the current level.

B. Public Comment

A 60 day notice was published in the **Federal Register** at 82 FR 51256, on November 3, 2017. One comment was received; however, it was not substantive, and did not change the estimate of the burden.

C. Annual Reporting Burden

Respondents: 100.

Responses per Respondent: 1.

Total Responses: 100.

Hours per Response: 1.

Total Burden Hours: 100.

Affected Public: Businesses or other for-profit and not-for-profit.

Respondent's Obligation: Required to obtain or retain benefits.

Reporting Frequency: On occasion.

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, telephone 202-501-4755. Please cite OMB Control No. 9000-0153, OMB Circular A-119, in all correspondence.

Dated: January 12, 2018.

Lorin S. Curit,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0890]

William Ralph Kincaid; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is denying William Ralph Kincaid's (Kincaid's) request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debaring Kincaid from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Kincaid was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Kincaid was given notice of the proposed debarment and an opportunity to request a hearing within

the timeframe prescribed by regulation. Kincaid submitted a request for hearing but failed to file with the Agency information and analysis sufficient to create a basis for a hearing.

DATES: This order is applicable January 18, 2018.

ADDRESSES: Any application by Kincaid for special termination of debarment under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application 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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: Your application must include the Docket No. FDA-2015-N-0890. An application will be placed in the docket and, unless 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.