The Federal Awardee Performance and Integrity Information System (FAPIIS) was developed to address these requirements. FAPIIS provides users access to integrity and performance information from the FAPIIS reporting module in the Contractor Performance Assessment Reporting System (CPARS), as well as proceedings information and suspension/debarment information from SAM. FAR provision 52.209–7, Information Regarding Responsibility Matters, requires information that is necessary to: (1) Determine the responsibility of prospective contractors; and (2) ensure that contractors maintain for accuracy and completeness, their integrity and performance information upon which responsibility determinations rely. Paragraph (b) of the provision contains a check box to be completed by the offeror indicating whether or not it has current active Federal contracts and grants with total value greater than $10,000,000. Paragraph (c) of the provision states that, if the offeror indicated in paragraph (b) that it has current active Federal contracts and grants with total value greater than $10,000,000, then, by submission of the offer, the offeror represents that the information entered into FAPIIS is current, accurate, and complete as of the date of submission of the offer.

FAR clause 52.209–9, Updates of Publicly Available Information Regarding Responsibility Matters, implements the requirement to keep FAPIIS up-to-date and the requirement of section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111–212), to make all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, publicly available. Paragraph (a) of the clause at 52.209–9 requires the contractor to update responsibility information on a semiannual basis, throughout the life of the contract, by posting the information in SAM. Paragraph (c) of the clause lets contractors know of their ability to provide feedback on information posted by the Government in FAPIIS and the procedure to follow in the event information exempt from public disclosure is slated to become publicly available information in FAPIIS.

4. Prohibition on Contracting with Inverted Domestic Corporations (FAR 52.209–2, 52.209–10, and 52.212–3(n)). Section 745 of Division D of the Consolidated Appropriations Act, 2008 (Pub. L. 110–161) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions) prohibit, on a Governmentwide basis, the use of appropriated (or otherwise made available) funds for contracts with either an inverted domestic corporation, or a subsidiary of such a corporation.

FAR provision 52.209–2,Prohibition on Contracting with Inverted Domestic Corporations-Representation, and its equivalent for commercial acquisitions at FAR provision 52.212–3(n), requires each offeror to represent whether it is, or is not, an inverted domestic corporation or a subsidiary of an inverted domestic corporation.

FAR clause 52.209–10, Prohibition on Contracting with Inverted Domestic Corporations, requires the contractor to promptly notify the contracting officer in the event the contractor becomes an inverted domestic corporation or a subsidiary of an inverted domestic corporation during the period of performance of the contract.

C. Annual Reporting Burden

Respondents/Recordkeepers: 1,333,801. (*1,328,450* respondents + 5,351 recordkeepers).

Total Annual Responses: 1,437,826.4.

Total Burden Hours: 1,511,005. (975,905 reporting hours + 535,100 recordkeeping hours).

Obtaining Copies: 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. 9000–0193, FAR Part 9 Responsibility Matters, in all correspondence.

Dated: May 21, 2019.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2019–11007 Filed 5–24–19; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0057; Docket No. 2019–0003; Sequence No. 5]

Submission for OMB Review; Evaluation of Export Offers

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 will be submitting to the Office of Management and Budget (OMB) a request to review and approve a revision and renewal of a previously approved information collection requirement concerning evaluation of export offers.

DATES: Submit comments on or before June 27, 2019.

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:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. Go to *http://www.regulations.gov* and follow the instructions on the site.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. ATTN: Ms. Mandell/IC 9000–0057, Evaluation of Export Offers.

Instructions: Please submit comments only and cite Information Collection ''Information Collection 9000–0057, Evaluation of Export Offers'' in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Curtis E. Glover, Sr., Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA, 202–501–4082 or via email at *Curtis.glover@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. OMB Number, Title, and Any Associated Form(s)

9000–0057, Evaluation of Export Offers

B. Needs and Uses

Offers submitted in response to Government solicitations must be evaluated and awards made on the basis of the lowest laid down cost to the Government at the overseas port of

discharge, via methods and ports compatible with required delivery dates and conditions affecting transportation known at the time of evaluation. FAR provision 52.247–51, ''Evaluation of Export Offers,'' is required for insertion in Government solicitations when supplies are to be exported through Contiguous United States (CONUS) ports and offers are solicited on a free onboard (f.o.b.) origin or f.o.b. destination basis. The provision has three alternates, to be used (1) when the CONUS ports of export are DoD water terminals, (2) when offers are solicited on an f.o.b. origin only basis, and (3) when offers are solicited on an f.o.b. destination only basis. The provision collects information regarding the offeror's preference for delivery ports. The information is used to evaluate offers [on the basis of shipment through the port resulting in the lowest cost to the Government.

C. Annual Reporting Burden

Respondents: 100.

Responses per Respondent: 4.

Annual Responses: 400.

Hours per Response: 0.25.

Total Burden Hours: 100.

D. Public Comment

A 60-day notice published in the **Federal Register** at 84 FR 5084 on February 20, 2019. No comments were received.

Obtaining Copies: 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 Number ''9000–0057, Evaluation of Export Offers,'' in all correspondence.

Dated: May 21, 2019.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2019–11004 Filed 5–24–19; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–0914]

Review and Update of Device Establishment Inspection Processes and Standards; 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 Agency) is extending the comment period for the notice of availability that appeared in the **Federal Register** on March 29, 2019. FDA requested comments on the draft guidance for industry entitled ''Review and Update of Device Establishment Inspection Processes and Standards.'' The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the document published March 29, 2019 (84 FR 11983). Submit either electronic or written comments on the draft guidance by June 27, 2019, to ensure that the Agency considers your comment on this draft guidance before it begins 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–2019–D–0914 for ''Review and Update of Device Establishment Inspection Processes and Standards.'' 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