saline intravenous bags is a commodity product, and prices typically are inversely correlated with the number of competitors in each market. As the number of suppliers offering a therapeutically equivalent drug increases, the price for that drug generally decreases due to the direct competition between the existing suppliers and each additional supplier. The Proposed Acquisition would combine two of only four significant companies selling the product, likely leading consumers to pay higher prices. Customers also have indicated that the presence of an independent Claris has allowed them to negotiate lower prices for fluconazole bags.

In addition, the Proposed Acquisition likely would cause significant anticompetitive harm to consumers by eliminating future competition that would otherwise have occurred if Baxter and Claris remained independent in the market for milrinone in dextrose intravenous bags. The evidence shows that the Proposed Acquisition, absent a remedy, would eliminate an additional independent entrant in the currently concentrated market for milrinone in dextrose intravenous bags, which would have enabled customers to negotiate lower prices. Customers and competitors have observed—and pricing data confirms—that the price of these pharmaceutical products decreases with new entry even after several other suppliers have entered the market. Thus, absent a remedy, the Proposed Acquisition likely will cause U.S. consumers to pay significantly higher prices for milrinone in dextrose intravenous bags in the future.

V. The Consent Agreement

The proposed Consent Agreement effectively remedies the competitive concerns raised by the acquisition in both markets at issue by requiring Claris to divest all its rights to fluconazole in saline intravenous bags and milrinone in dextrose intravenous bags to Renaissance. Renaissance is a pharmaceutical corporation that develops, manufacturers, sells, and distributes injectable pharmaceutical products in the United States. The parties must accomplish these divestitures no later than ten days after they consummate the Proposed Acquisition.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisition. If the Commission determines that Renaissance is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to Renaissance and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The proposed Consent Agreement and Order contain several provisions to help ensure that the divestitures are successful. Baxter will supply Renaissance with fluconazole in saline intravenous bags and milrinone in dextrose intravenous bags for up to five years while the company transfers the manufacturing technology to Renaissance or its contract manufacturing designee. The proposed Order also requires Baxter to provide transitional services to Renaissance to assist it in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. These transitional services include technical assistance to manufacture fluconazole in saline intravenous bags and milrinone in dextrose intravenous bags in substantially the same manner and quality employed or achieved by Claris. It also includes advice and training from knowledgeable employees of the parties. Under the proposed Consent Agreement, the Commission also will appoint an Interim Monitor.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2017–16017 Filed 7–28–17; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0024; Docket 2017–0053; Sequence 2]

Information Collection; Federal Acquisition Regulation: Buy American, Trade Agreements, and Duty-Free Entry

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, the Regulatory Secretariat Division (MVCB) will be submitting to the Office of Management and Budget (OMB) a request for revision and an extension to existing OMB clearances regarding the Buy American statute, Trade Agreements, and duty-free entry.

DATES: Submit comments on or before September 29, 2017.

ADDRESSES: Submit comments identified by Information Collection 9000–0024, Buy American, Trade Agreements, and Duty-Free Entry, 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 9000–0024. Select the link ''Comment Now'' that corresponds with ''Information Collection 9000–0024, Buy American, Trade Agreements, and Duty-Free Entry. Follow the instructions provided on the screen. Please include your name, company name (if any), and ''Information Collection 9000–0024, Buy American, Trade Agreements, and Duty-Free Entry'' on your attached document.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Sosa/IC 9000–0024, Buy American, Trade Agreements, and Duty-Free Entry.

Instructions: Please submit comments only and cite Information Collection 9000–0024, Buy American, Trade Agreements, and Duty-Free Entry, 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: Ms. Cecelia L. Davis, Procurement Analyst, Acquisition Policy Division, GSA (202) 219–0202 or email *cecelia.davis@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. This information collection requirement pertains to information that an offeror must submit in response to

the requirements of the provisions and clauses in FAR 52.225 that relate to the following:

* The Buy American statute (41 U.S.C. chapter 83 and E.O. 10582).

* The Trade Agreements Act (19 U.S.C. 2501–2515), including the World Trade Organization Government Procurement Agreement and various free trade agreements.

* The American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5) (Recovery Act).

* Subchapters VIII and X of Chapter 98 of the Harmonized Tariff Schedule of the United States (19 U.S.C. 1202).

a. 52.225–2, Buy American Certificate, as prescribed in FAR 25.1101 (a)(2), requires the offeror to identify in its proposal supplies that do not meet the definition of domestic end product. The Buy American statute does not apply to acquisitions of commercial information technology.

b. 52.225–4, Buy American—Free Trade Agreements—Israeli Trade Act Certificate, as prescribed in FAR 25.1101(b)(2)(i), requires separate listing of foreign products that are eligible under a trade agreement, and listing of all other foreign end products.

c. 52.225–6, Trade Agreements Certificate, as prescribed in FAR 25.1101(c)(2), requires the offeror to certify that all end products are either U.S.-made or designated country end products, except as listed in paragraph (b) of the provision. Offerors are not allowed to provide other than a U.S.-made or designated country end product, unless the requirement is waived.

d. *Construction provisions and clauses:*

- 52.225–9, Buy American–Construction Materials
- 52.225–10, Notice of Buy American Requirement—Construction Materials
- 52.225–11, Buy American—Construction Materials under Trade Agreements
- 52.225–12, Notice of Buy American Requirement—Construction Materials under Trade Agreements
- 52.225–21, Required Use of American Iron, Steel and Manufactured Goods—Buy American—Construction Materials
- 52.225–23, Required Use of American Iron, Steel and Manufactured Goods—Buy American—Construction Materials under Trade Agreements.

The listed provisions and clauses, as prescribed in FAR 25.1102(a) through (e), provide that an offeror/contractor requesting to use foreign construction material due to unreasonable cost of domestic construction material shall provide adequate information to permit evaluation of the request.

e. 52.225–8, Duty-Free Entry (formerly OMB clearance 9000–0022), as prescribed in FAR 25.1101(e), requires the contractor to notify the contracting officer when it purchases foreign supplies, in order to determine whether the supplies should be duty-free. In addition, all shipping documents and containers must specify certain information to assure the duty-free entry of the supplies.

B. Annual Reporting Burden

1. *Buy American and Trade Agreements-Supplies:*

FAR Clause 52.225–2, Buy American Certificate, requires the offeror to identify in its proposal supplies for use in the United States that do not meet the definition of domestic end product. The Buy American statute does not apply to acquisitions of commercial information technology.

Respondents: 3,306.
Responses per Respondent: 5.
Total Responses: 16,530.
Hours per Response: .25.
Total Burden Hours: 4,133.

FAR Clause 52.225–4, Buy American-Free Trade Agreements-Israeli Trade Act Certificate, requires separate listing of foreign products that are eligible under a trade agreement, and listing of all other foreign end products.

Respondents: 1,977.
Responses per Respondent: 5.
Total Responses: 9,885.
Hours per Response: .25.
Total Burden Hours: 2,471.

FAR Clause 52.225–6, Trade Agreements Certificate, requires the offeror to certify that all end products are either U.S.-made or designated country end products, except as listed in paragraph (b) of the provision. Offerors are not allowed to provide other than a U.S.-made or designated country end product, unless the requirement is waived.

Respondents: 397.
Responses per Respondent: 2.
Total Responses: 794.
Hours per Response: .25.
Total Burden Hours: 199.

2. Buy American and Trade Agreements—Construction provisions and clauses provide that an offeror/contractor requesting to use foreign construction material due to unreasonable cost of domestic construction material shall provide adequate information to permit evaluation of the request.

—52.225–9, Buy American—Construction Materials
—52.225–10, Notice of Buy American Requirements—Construction Materials
—52.225–11, Buy American—Construction Materials under Trade Agreements
—52.225–12, Notice of Buy American Requirements—Construction Materials under Trade Agreements
—52.225–21, Required Use of American Iron, Steel and Manufactured Goods—Buy American—Construction Materials
—52.225–23, Required Use of American Iron, Steel and Manufactured Goods—Buy American—Construction Materials under Trade Agreements

Respondents: 853.
Responses per Respondent: 2.3.
Total Responses: 1,990.
Hours per Response: 5.
Total Burden Hours: 10,045.

3. Duty-Free Entry. The clause at FAR 52.225–8, Duty-Free Entry (formerly OMB clearance 9000–0022), is included in solicitations and contracts for supplies that may be imported into the United States and for which duty-free entry may be obtained in accordance with FAR 25.903(a), if the value of the acquisition (1) exceeds the simplified acquisition threshold; or (2) does not exceed the simplified acquisition threshold, but the savings from waiving the duty is anticipated to be more than the administrative cost of waiving the duty. The contracting officer analyzes the information submitted by the contractor to determine whether or not supplies should enter the country duty-free.

Respondents: 1,330.
Responses per Respondent: 10.
Total Responses: 13,300.
Hours per Response: 0.5.
Total Burden Hours: 6,650.

4. Summary

Respondents: 7,863.
Responses per Respondent: 5.4.
Total Responses: 42,499.
Hours per Response: .5.
Total Burden Hours: 23,497.

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, telephone 202–501–4755.

Please cite OMB Control No. 9000–0024, Buy American, Trade Agreements, and Duty-Free Entry in all correspondence.

Dated: July 25, 2017.

Lorin S. Curit,

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

[FR Doc. 2017–16022 Filed 7–28–17; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10110]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by September 29, 2017.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development Attention: Document Identifier/OMB Control Number _____Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10110 Manufacturer Submission of Average Sales Prices (ASP) Data for Medicare Part B Drugs

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. The term ''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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection;

Title of Information Collection: Manufacturer Submission of Average Sales Prices (ASP) Data for Medicare Part B Drugs; *Use:* In accordance with Section 1847A of the Social Security Act (the Act), Medicare Part B covered drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price (ASP) of the drug or biological, beginning in Calendar Year (CY) 2005. The ASP data reporting requirements are specified in Section 1927 of the Act. The reported ASP data are used to establish the Medicare payment amounts. *Form Number:* CMS–10110 (OMB control number: 0938–0921); *Frequency:* Quarterly; *Affected Public:* Business or other For-profits; *Number of Respondents:* 180; *Total Annual Responses:* 720; *Total Annual Hours:* 9360. (For policy questions regarding this collection contact Felicia Eggleston at 410–786–9287.)

Dated: July 25, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–16016 Filed 7–28–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–7045–N]

Health Insurance Marketplace℠, Medicare, Medicaid, and Children's Health Insurance Programs; Announcement of the Renewal of the Charter for the Advisory Panel on Outreach and Education (APOE)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the renewal of the charter of the Advisory Panel on Outreach and Education APOE (the Panel) in accordance with the Federal Advisory Committee Act. The Panel advises and makes recommendations to the Secretary of the U.S. Department of Health and Human Services (HHS) and the Administrator of the Centers for Medicare & Medicaid