

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

9000–0163, Small Business Size Rerepresentation.

B. Needs and Uses

This clearance covers the information that contractors must submit to comply with the following Federal Acquisition Regulation (FAR) requirements:

52.219–28, *Post-Award Small Business Program Rerepresentation*. This clause requires contractors who originally represented themselves as a small business for a contract award to rerepresent their size and socioeconomic status at the prime contract level by updating their representations in the Representations and Certifications section of the System for Award Management (SAM). Contractors are also required to notify the contracting officer by email, or otherwise in writing, that the rerepresentations have been made, and provide the date on which they were made.

Small business contractors are required to rerepresent their size and socioeconomic status upon occurrence of any of the following:

- Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include FAR clause 52.219–28 if the novation agreement was executed prior to inclusion of this clause in the contract.
- Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include FAR clause 52.219–28 if the merger or acquisition occurred prior to inclusion of this clause in the contract.
- For long-term contracts—
Within 60 to 120 days prior to the end of the fifth year of the contract; and
Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.
- When contracting officers explicitly require it for an order issued under a multiple-award contract.

The collected information is used by the Small Business Administration, Congress, Federal agencies and the general public for various reasons such as determining if agencies are meeting statutory goals, set-aside determinations, and market research.

C. Annual Burden

Respondents: 2,647.

Total Annual Responses: 4,029.

Total Burden Hours: 2,014.5.

D. Public Comment

A 60-day notice was published in the **Federal Register** at 86 FR 8019, on February 3, 2021. No comments were received.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing GSARegSec@gsa.gov. Please cite OMB Control No. 9000–0163, Small Business Size Rerepresentation.

Janet Fry,

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

[FR Doc. 2021–07568 Filed 4–13–21; 8:45 am]

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

[OMB Control No. 9000–0188; Docket No. 2021–0053; Sequence No. 3]

**Submission for OMB Review;
Combating Trafficking in Persons**

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 has submitted 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 regarding combating trafficking in persons.

DATES: Submit comments on or before May 14, 2021.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

Additionally, submit a copy to GSA through <http://www.regulations.gov> and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments.

Instructions: All items submitted must cite OMB Control No. 9000–0188, Combating Trafficking in Persons. 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. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or GSARegSec@gsa.gov.

FOR FURTHER INFORMATION CONTACT: Zenaida Delgado, Procurement Analyst, at telephone 202–969–7207, or zenaida.delgado@gsa.gov.

SUPPLEMENTARY INFORMATION:**A. OMB Control Number, Title, and Any Associated Form(s)**

9000–0188, Combating Trafficking in Persons.

B. Need and Uses

This clearance covers the information that offerors contractors must submit to comply with the following Federal Acquisition Regulation (FAR) requirements:

52.222–50, Combating Trafficking in Persons.

Notification. Paragraph (d) of this clause requires contractors to notify the contracting officer and the agency Inspector General of—

- Any credible information they receive from any source that alleges a contractor employee, subcontractor, or subcontractor employee, or their agent has engaged in conduct that violates the policy in paragraph (b) of the clause 52.222–50; and
- Any actions taken against a contractor employee, subcontractor, subcontractor employee, or their agent pursuant to this clause.

Compliance Plan and Annual Certification. Paragraph (h) of the clause contains an additional requirement for contracts for supplies (other than commercially available off-the-shelf (COTS) items) to be acquired outside the United States and contracts for services to be performed outside the United States, with an estimated value exceeding \$550,000, where the contractor is to maintain a compliance plan during the performance of the contract. This compliance plan must include an awareness program, a process for employees to report activity inconsistent with the zero-tolerance policy, a recruitment and wage plan, a housing plan, and procedures to prevent

subcontractors from engaging in trafficking in persons.

- Contractors are required to provide the compliance plan to the contracting officer upon request.

- Contractors are required to submit a certification to the contracting officer annually after receiving an award, asserting that they have the required compliance plan in place and that there have been no abuses, or that appropriate actions have been taken if abuses have been found.

- For those subcontractors required to submit a certification (see next bullet on flow down), contractors shall require that submission prior to award of the subcontract and annually thereafter.

Portions of this clause flows down to all subcontractors. The requirements related to the compliance plan only flow down to subcontracts exceeding \$550,000 for supplies (other than COTS items) acquired and services performed outside the United States.

This clause applies to commercial item acquisitions, except the portions related to the compliance plan do not apply to acquisitions of COTS items.

52.222–56, *Certification Regarding Trafficking in Persons Compliance Plan*.

This provision requires apparently successful offerors to submit a certification, prior to award, that they have implemented a compliance plan and that there have been no abuses, or that appropriate actions have been taken if abuses have been found.

The provision requires this certification for the portion of contracts exceeding \$550,000 for supplies (other than COTS items) acquired and services performed outside the United States.

This provision applies to commercial item acquisitions, except acquisitions of COTS items.

FAR 52.222–50, paragraph (d)—Notification. The Government uses this notification of potential violations of trafficking in persons requirements to investigate and take appropriate action if a violation has occurred.

FAR 52.222–50, paragraph (h)—Compliance Plan. The Government uses the compliance plan to ascertain compliance with the Trafficking Victims Protection Act (22 U.S.C. 7104), Executive Order 13627, or any other applicable law or regulation.

FAR 52.222–50, paragraph (h) and FAR 52.222–56—Certification. The Government uses the certification to obtain reasonable assurance that the contractor and its subcontractors are aware of and complying with the requirements of the Executive Order and statute.

C. Annual Burden

Respondents/Recordkeepers: 5,876.

Total Annual Responses: 11,702.

Total Burden Hours: 164,154. (25,722 reporting hours + 138,432 recordkeeping hours)).

D. Public Comment

A 60-day notice was published in the **Federal Register** at 86 FR 8360, on February 5, 2021. No comments were received.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing GSARegSec@gsa.gov.

Please cite OMB Control No. 9000–0188, Combating Trafficking in Persons.

Janet Fry,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0998]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by May 14, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information

collection is 0910–0409. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring—21 CFR part 315

OMB Control Number 0910–0409—Extension

This information collection supports our regulations in part 315 (21 CFR part 315) that require manufacturers of diagnostic radiopharmaceuticals to submit information that demonstrates the safety and effectiveness of: (1) A new diagnostic radiopharmaceutical; or (2) a new indication for use of an approved diagnostic radiopharmaceutical. Information about the safety or effectiveness of a diagnostic radiopharmaceutical enables us to properly evaluate the safety and effectiveness profiles of such radiopharmaceuticals.

The information, which is usually submitted as part of a new drug application (NDA) or biologics license application (BLA) or as a supplement to an approved application typically includes, but is not limited to, nonclinical and clinical data on the pharmacology; toxicology; adverse events; radiation safety assessments; and chemistry, manufacturing, and controls. The content and format of an application for approval of a new drug are set forth in § 314.50 (21 CFR 314.50) and have been approved under OMB control number 0910–0001. This information collection supports part 315, which is currently approved under OMB control number 0910–0409.

In table 1, row 1, we estimate the annual reporting burden for preparing the safety and effectiveness sections of an application. This estimate does not include the time needed to conduct studies and clinical trials or other research from which the reported information is obtained.

Based on past submissions of human drug applications, new indication supplements for diagnostic