DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0154; Docket No. 2021–0053; Sequence No. 7]

Submission for OMB Review; Construction Wage Rate Requirements—Price Adjustment (Actual Method)

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 extension of a previously approved information collection requirement regarding construction wage rate requirements—price adjustment (Actual Method).

DATES: Submit comments on or before July 26, 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. 9000–0154, Construction Wage Rate Requirements—Price Adjustment (Actual Method). 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)

9000–0154, Construction Wage Rate Requirements—Price Adjustment (Actual Method).

B. Need and Uses

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

- 52.222–32, Construction Wage Rate Requirements—Price Adjustment (Actual Method). This clause requires contractors to submit at the exercise of each option to extend the term of the contract, a statement of the amount claimed for incorporation of the most current Department of Labor wage determination, and any relevant supporting data, including payroll records, that the contracting officer may reasonably require.

Contracting officers use the information to establish the contract's construction requirements price adjustment to reflect the contractor's actual increase or decrease in wages and fringe benefits.

C. Annual Burden

Respondents: 506.

Total Annual Responses: 506.

Total Burden Hours: 20,240.

D. Public Comment

A 60-day notice was published in the **Federal Register** at 86 FR 20699, on April 21, 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. 9000–0154, Construction Wage Rate Requirements—Price Adjustment (Actual Method).

William Clark,

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

[FR Doc. 2021–13628 Filed 6–24–21; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Delegation of Authority

Notice is hereby given that I have delegated the authority to designate chairs and invite members to serve on the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel to the Centers for Disease Control and Prevention Director (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) Administrator. This authority may be redelegated by the CDC Director, or the ATSDR Administrator.

This delegation became effective upon date of signature. In addition, I hereby affirm and ratify any actions taken by you or your subordinates that involved the exercise of the authorities delegated herein, or substantially similar authorities vested in me by prior annual HHS appropriations acts, prior to the effective date of the delegation.

Dated: June 15, 2021.

Xavier Becerra,

Secretary.

[FR Doc. 2021–13605 Filed 6–24–21; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0386]

Agency Information Collection Activities; Proposed Collection; Comment Request; Class II Special Controls for Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on class II special controls for human immunodeficiency

virus (HIV) serological diagnostic and supplemental tests and HIV nucleic acid (NAT) diagnostic and supplemental tests.

DATES: Submit either electronic or written comments on the collection of information by August 24, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 24, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 24, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2021–N–0386 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Class II Special Controls for Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

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, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''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 (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Class II Special Controls for Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests

OMB Control Number 0910–NEW

In the **Federal Register** of February 21, 2020 (85 FR 10110), we published a proposed order to reclassify certain HIV serological diagnostic and supplemental tests and HIV NAT diagnostic and supplemental tests from class III (premarket approval) into class II (special controls) (the proposed order). In the proposed order, FDA proposed special controls that the Agency believes are necessary to provide a

reasonable assurance of safety and effectiveness for these devices. The proposed special controls would require the submission of a log of all complaints annually for a period of 5 years following FDA clearance of a traditional premarket notification (510(k)) submission for a device within the scope of the proposed order.

Currently, manufacturers of HIV serological diagnostic and supplemental tests and HIV NAT diagnostic and supplemental tests are subject to FDA regulations in part 820 (21 CFR part 820), which govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. Manufacturers are required to maintain complaint files and to review and evaluate complaints for these devices under § 820.198 (21 CFR 820.198).

Complaints required to be reported in the annual logs under the proposed special controls, such as certain complaints involving unusually high invalid rates or issues with users conducting the test, may not meet the definition of a medical device report required to be reported to FDA under 21 CFR part 803 (medical device reporting; currently approved under OMB control number 0910–0437), but could potentially affect the safety and efficacy of these devices. If the proposed order is finalized, we intend to review the information in the complaint logs in a timely manner and engage with manufacturers as necessary. The submission of the complaint log would provide us with earlier notification of concerns and enable us to determine whether they have been adequately addressed. The Agency usually would not evaluate this kind of complaint information until an FDA inspection, which typically occurs less frequently than annually. We believe implementing these specific reporting measures as part of the special controls would be necessary to provide a reasonable assurance of safety and effectiveness for HIV diagnostic and supplemental tests subject to the proposed order.

Description of Respondents: The respondents to the information collection are manufacturers of HIV diagnostic and supplemental test devices that would be subject to the proposed order, if finalized.

Finalizing the proposed order would add classification regulations for these devices in 21 CFR part 866 (Immunology and Microbiology Devices) at 21 CFR 866.3956 for the HIV serological diagnostic and supplemental tests, and 21 CFR 866.3957 for the HIV NAT diagnostic and supplemental tests, and establish special controls necessary to provide reasonable assurance of their safety and effectiveness. As described above, the special controls would require the submission of a log of all complaints annually for a period of 5 years following FDA clearance of a traditional 510(k) submission for one of these devices.

We estimate the reporting burden hours associated with the proposed order, if finalized, to be approximately 30 reporting burden hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR citation, activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Proposed 21 CFR 866.3956(b)(1)(iii) and 866.3957(b)(1)(iii), Submission of log to FDA	10	1	10	3	30

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate of the average burden per response on our experience with other types of annual report submissions. We base our estimate of the number of affected respondents on the expected number of manufacturers that would be submitting a 510(k) for a new device or changes to an existing device that would require a 510(k).

As noted above, manufacturers of the devices subject to the proposed order must already maintain complaint files and review and evaluate complaints under § 820.198. If the proposed order is finalized as proposed, we estimate it would take a manufacturer approximately 3 hours annually to review their existing records, prepare the complaint log, and submit it to FDA. Although respondents may submit the information electronically through the FDA Electronic Submission Gateway, on paper, or electronic media (*e.g.,* CD, DVD) to the Center for Biologics Evaluation and Research's Document Control Center, we assume that all manufacturers will submit their logs electronically.

Dated: June 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13580 Filed 6–24–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1802]

Cancer Clinical Trial Eligibility Criteria: Approach to Available Therapy in Non-Curative Settings; Draft Guidance for Sponsors; 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 draft guidance for sponsors entitled ''Cancer Clinical Trial Eligibility Criteria: Approach to Available Therapy in Non-Curative Settings.'' The draft guidance provides recommendations to sponsors of clinical trials of investigational cancer drugs regarding the inclusion of patients who have not previously received available therapy (commonly referred to as existing treatment options) for their cancer in the non-curative setting. The draft guidance is intended to facilitate increased clinical trial options for patients with non-curable cancers by recognizing that, with appropriate informed consent, it may be reasonable for patients to be eligible for inclusion in trials of investigational cancer drugs, regardless of whether they have received available therapy, in the non-curative setting.

DATES: Submit either electronic or written comments on the draft guidance by August 24, 2021 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: