

rules with a new framework under which: (a) packet-based services, time division multiplexing (TDM) services with bandwidth greater than 45 mbps, and TDM transport services are not subject to ex ante pricing regulation; (b) a new standard is applied to determine the extent to which the Commission regulates price cap LECs' TDM end user channel terminations with bandwidth less than 45 mbps and certain other low bandwidth business data services. Under this standard, a price cap LEC is not subject to ex ante pricing regulation in the provision of these services in counties deemed competitive under the Commission's competitive market test or for which the price cap LEC previously obtained Phase II pricing flexibility; (c) the price cap LEC is subject to ex ante pricing regulation in other counties where it is the incumbent LEC, but in these counties the price cap LEC has downward pricing flexibility (*i.e.*, the equivalent of Phase I pricing flexibility under the prior rules); and (d) the Commission will update the competitive market test results every three years using data already collected in FCC Form 477.

Among other rules changes, the *Business Data Services Report and Order* repealed section 1.774, which set forth requirements for pricing flexibility applications, and added section 1.776, which limits the circumstances under which price cap LECs must file their business data services contracts as contract-based tariffs. The Commission also amended section 69.701 of its rules to specify that its pricing flexibility rules no longer apply to business data services.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

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OFFICE OF MANAGEMENT AND BUDGET

Office of Federal Procurement Policy

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000-0095; Docket No. 2025-0087; Sequence No. 1]

Information Collection; Federal Acquisition Regulation Part 27 Requirements

AGENCY: Office of Federal Procurement Policy (OFPP), Office of Management and Budget (OMB); Department of Defense (DOD); General Services Administration (GSA); and National Aeronautics and Space Administration (NASA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and OMB regulations, OFPP, DoD, GSA, and NASA invite the public to comment on an extension concerning Federal Acquisition Regulation part 27 requirements. OFPP, DoD, GSA, and NASA invite comments on: whether the proposed collection of information is necessary for the proper performance of the functions of Federal Government acquisitions, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. OMB has approved this information collection for use through February 28, 2026. OFPP, DoD, GSA, and NASA propose that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: OFPP, DoD, GSA, and NASA will consider all comments received by February 10, 2026.

ADDRESSES: OFPP, DoD, GSA, and NASA invite interested persons to submit comments on this collection through <https://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. If there are

difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202-501-4755 or GSARegSec@gsa.gov.

Instructions: All items submitted must cite OMB Control No. 9000-0095, Federal Acquisition Regulation Part 27 Requirements. Comments received generally will be posted without change to <https://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.

FOR FURTHER INFORMATION CONTACT: FARPolicy@gsa.gov or call 202-969-4075.

SUPPLEMENTARY INFORMATION:

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

9000-0095, Federal Acquisition Regulation Part 27 Requirements

B. Need and Uses

This clearance covers the following information that offerors and contractors must submit in response to the requirements of the provisions and clauses in the Federal Acquisition Regulation (FAR) part 27, as codified in Chapter 1 of Title 48 of the Code of Federal Regulations:

FAR 52.227-2, Notice and Assistance Regarding Patent and Copyright Infringement. This clause requires contractors to notify the Government of any allegations of patent or copyright infringement arising during the performance of the contract. The clause requires contractors to furnish, when requested by the contracting officer, all evidence and information in the contractor's possession regarding such a claim or suit. This clause flows down to subcontracts that are expected to exceed the simplified acquisition threshold (SAT—currently \$350,000).

FAR 52.227-6, Royalty Information. This provision requires offerors to report all royalties anticipated or paid in excess of \$250 for the use of patented inventions by furnishing:

- (1) Name and address of licensor.
- (2) Date of license agreement.
- (3) Patent numbers, patent application serial numbers, or other basis on which the royalty is payable.
- (4) Brief description, including any part or model numbers of each contract item or component on which the royalty is payable.
- (5) Percentage or dollar rate of royalty per unit.
- (6) Unit price of contract item.
- (7) Number of units.

(8) Total dollar amount of royalties.

Also, the contracting officer may ask the offeror to provide a copy of the current license agreement identifying claims to specific patents.

FAR 52.227–9, Refund of Royalties. This clause requires contractors to furnish to the contracting officer, before final payment under a contract, a statement of royalties paid or required to be paid in connection with performing the contract. The clause requires contractors to notify the contracting officer if the contractor is relieved, within three years after final payment under the contract, from payment of royalties included in the final contract price. This clause flows down to subcontracts in which the amount of royalties reported during negotiation of the subcontract exceeds \$250.

FAR 52.227–11, Patent Rights—Ownership by the Contractor, or 52.227–13, Patent Rights—Ownership by the Government—Commerce Patent Regulations. These FAR clauses require a Government contractor to report all inventions made in the performance of work under a Government contract or subcontract for experimental, developmental, or research work to the contracting officer, submit a disclosure of the invention, and identify any publication, sale, or public use of the invention (52.227–11(c), 52.227–13(e)(1)). The contracting officer may modify 52.227–11(e) or otherwise supplement the clause to require contractors to submit periodic or interim and final reports listing subject inventions (27.303(b)(2)(i) and (ii)). The contracting officer may also require a contractor, under FAR 52.227–11, to: provide the filing date, serial number, title, patent number and issue date for any patent application filed on any subject invention in any country or, upon request, copies of any patent application so identified; and furnish the Government an irrevocable power to inspect and make copies of the patent application file when a Government employee is a co-inventor. (27.303(b)(2)(iv) and (v)). In order to ensure that subject inventions are reported, the contractor is required to establish and maintain effective procedures for identifying and disclosing subject inventions (52.227–11, Alternate IV; 52.227–13(e)(1)). In addition, the contractor must require its employees, by written agreements, to disclose subject inventions (52.227–11(e)(2); 52.227–13(e)(4)). The contractor also has an obligation to utilize the subject invention, and agree to report, upon request, the utilization

or efforts to utilize the subject invention (27.302(e); 52.227–11(f)).

FAR 52.227–14, Rights in Data—General. This clause enables the contractor to protect qualifying limited rights data and restricted computer software by withholding the data from the Government and instead delivering form, fit, and function data. For unauthorized marking of data, the contractor may provide written justification to substantiate the propriety of the markings for the contracting officer to consider whether or not the markings are to be canceled or ignored. For omitted or incorrect markings of data that has not been disclosed without restriction outside the Government, the contractor may request, within 6 months (or a longer time approved by the contracting officer) after delivery of the data, permission to have authorized notices placed on the data at the contractor's expense. Contractors shall obtain from their subcontractors all data and rights necessary to fulfill the contractor's obligations to the Government under the contract. If a subcontractor refuses to accept terms affording the Government those rights, the contractor shall notify the contracting officer of the refusal.

FAR 52.227–15, Representation of Limited Rights Data and Restricted Computer Software. This provision requires an offeror to represent that it has reviewed the requirements for the delivery of technical data or computer software and state, in response to a solicitation, whether data proposed for fulfilling the data delivery requirements qualifies as limited rights data or restricted computer software. If the Government does not receive unlimited rights, the offeror must provide a list of the data that qualify as limited rights data or restricted computer software. The offeror would identify any proprietary data it would use during contract performance, in order that the contracting officer might ascertain if such proprietary data should be delivered.

FAR 52.227–16, Additional Data Requirements. This clause requires contractors to keep, for possible delivery to the Government, any data, in addition to data already required to be delivered under the contract, first produced or specifically used in performance of the contract for a period of three years from the final acceptance of all items delivered under the contract. The data delivered under this clause may be in the form of computations, preliminary data, records of experiments, etc. For any data to be delivered under this clause, the Government will pay the contractor for converting the data into a

specific form, and for reproducing and delivering the data. The purpose of such recordkeeping requirements is to ensure that, if all data requirements are not known prior to contract award, the Government can fully evaluate the research in order to ascertain future activities and to insure that the research was completed and fully reported, as well as to give the public an opportunity to assess the research results and secure any additional information.

FAR 52.227–17, Rights in Data—Special Works. This clause is included in solicitations and contracts primarily for production or compilation of data. It is used in rare and exceptional circumstances to permit the Government to limit the contractor's rights in data by preventing the release, distribution, and publication of any data first produced in the performance of the contract. This clause may also be limited to particular items and not the entire contract. This clause requires contractors to assign (with or without registration), or obtain the assignment of, the copyright to the Government or its designated assignee.

FAR 52.227–18, Rights in Data—Existing Works. This clause is used when the Government is acquiring existing audiovisual or similar works, such as books, without modification. This clause requires contractors to obtain a license for the Government to reproduce, prepare derivative works, and perform and display publicly the materials.

FAR 52.227–19, Commercial Computer Software License. This clause requires contractors to affix a notice on any commercial software delivered under the contract that provides notice that the Government's rights regarding the data are set forth in the contract.

FAR 52.227–20, Rights in Data—SBIR Program. This clause authorizes contractors under Small Business Innovation Research (SBIR) contracts to affix a notice to SBIR data delivered under the contract to limit the Government's rights to disclose data first produced under the contract. For omitted or incorrect markings of data that has not been disclosed without restriction outside the Government, the contractor may request, within 6 months (or a longer time approved by the contracting officer) after delivery of the data, permission to have authorized notices placed on the data at the contractor's expense. Contractors shall obtain from their subcontractors all data and rights necessary to fulfill the contractor's obligations to the Government under the contract. If a subcontractor refuses to accept terms affording the Government those rights,

the contractor shall notify the contracting officer of the refusal.

FAR 52.227–21, Technical Data Declaration, Revision, and Withholding of Payment—Major Systems. This clause requires major systems contractors to certify that the data delivered under the contract is complete, accurate, and compliant with the requirements of the contract.

FAR 52.227–23, Rights to Proposal Data (Technical). This clause allows the Government to identify pages of a proposal that would not be subject to unlimited rights in the technical data.

The information collected is used to protect the Government's rights and interests.

C. Annual Burden

Respondents/Recordkeepers: 830.

Total Annual Responses: 14,848.

Total Burden Hours: 55,600. (54,673 reporting hours + 927 recordkeeping hours).

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. 9000–0095, Federal Acquisition Regulation Part 27 Requirements.

Janet Fry,

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

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BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–5997]

Biosimilar User Fee Act; Stakeholder Consultation Meetings on Biosimilar User Fee Act Reauthorization; Request for Notification of Stakeholder Intention To Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this notice to request that public stakeholders—including patient and consumer advocacy groups—notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Biosimilar User

Fee Act (BsUFA). The statutory authority for BsUFA expires in September 2027. At that time, new legislation will be required for FDA to continue collecting biosimilar biological product user fees in future fiscal years. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next BsUFA program. The FD&C Act also requires that FDA hold discussions at least once every month with patient and consumer advocacy groups during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings by January 30, 2026. Stakeholder meetings will be held monthly. It is anticipated that they will commence in April 2026. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: Submit notification of intention to participate in monthly stakeholder meetings by email to BSUFAReauthorization@fda.hhs.gov. The meetings will be held in person at the FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, and virtually using the Microsoft Teams platform. In-person participants must be REAL ID compliant to access federal facilities. For additional information regarding REAL ID, refer to <https://www.dhs.gov/real-id/real-id-faqs>. Entrance for the stakeholder meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/about-fda/visitor-information>.

FOR FURTHER INFORMATION CONTACT:

Thamar Bailey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 32, Rm. 4103, Silver Spring, MD 20993–0002, 301–796–6645, BSUFAReauthorization@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that public stakeholders—including patient and consumer advocacy groups—notify the Agency of their intent to participate in periodic stakeholder consultation meetings on the reauthorization of BsUFA. BsUFA authorizes FDA to

collect user fees from the regulated industry to support the process for the review of biosimilar biological products. The authorization for the current program (BsUFA III) expires in September 2027. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years.

Section 744I(f)(1) of the FD&C Act (21 U.S.C. 379j–53(f)(1)) requires that FDA consult with a range of stakeholders, including representatives from patient and consumer advocacy groups, in developing recommendations for the next BsUFA program. FDA will initiate the reauthorization process by holding a public meeting on December 3, 2025, where stakeholders and other members of the public will be given an opportunity to present their views on the reauthorization (90 FR 52967, November 24, 2025). Section 744I(f)(3) of the FD&C Act (21 U.S.C. 379j–53(f)(3)) further requires that FDA continue meeting with representatives from patient and consumer advocacy groups at least once every month during negotiations with the regulated industry to continue discussions of these stakeholders' views on the reauthorization. It is anticipated that these monthly stakeholder consultation meetings will commence in April 2026.

FDA is issuing this **Federal Register** notice to request that representatives from patient and consumer advocacy groups notify FDA of their intent to participate in the periodic stakeholder consultation meetings on BsUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensure progress in these discussions. If you wish to participate in these stakeholder consultation meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions. Stakeholders who identify themselves through this notice will be included in all patient and consumer advocacy group stakeholder consultation discussions while FDA negotiates with the regulated industry. If a representative from a patient or consumer advocacy group decides to participate in these monthly meetings at a later time, that stakeholder may join the remaining monthly patient and consumer advocacy group stakeholder consultation meetings after notifying FDA of this intention (see **ADDRESSES**). These stakeholder discussions will satisfy the consultation requirement in section 744I(f)(3) of the FD&C Act.