

**Title: Application of Artificial Intelligence and Computational Statistics for Biosimilar Product Quality Characterization**

The U.S. Food & Drug Administration (FDA) has a requirement to provide AI Analysis Services.

**PRICING SCHEDULE**

<b>CLIN</b>	<b>Item #</b>	<b>Qty</b>	<b>Price</b>
<b>0001</b>	<b>A-1 Based Image Analysis for Bio-similars (FlowCam)</b>	<b>1</b>	
<b>0002</b>	<b>A-1 Based Image Analysis for Bio-similars (BMI)</b>	<b>1</b>	
<b>Total Cost</b>			

**Background**

The Division of Product Quality Research (DPQR) conducts studies to understand the impact of changes in specifications of bulk drug substance and ingredients, formulation, packaging, manufacturing equipment, and processes on product quality attributes. DPQR research is aligned with Center for Drug Evaluation and Research (CDER) and the Office of Pharmaceutical Quality's (OPQ) priorities including encouraging innovation in the pharmaceutical sector. Aggregation and particulates are a challenge to development of biologics and biosimilar products. Optical image analysis is a common employed for quality assessment and characterization of subvisible and visible particles in biosimilar drug products. DPQR is currently conducting research to fully harness the large amount of information encoded in images of aggregates and particulates in biosimilar products. To this end, DPQR is seeking AI analysis service to support ongoing project in detection and classification of particles in biosimilar drug products.

**Objective**

DPQR requires artificial intelligence analysis services to detect and classify particles in biosimilar drug products as part of a feasibility study to assess the utility of Artificial Intelligence/Machine Learning and computational statistical analysis for biosimilar quality assessment and quality surveillance.

## Requirements

- Apply supervised and unsupervised machine learning approaches (e.g. deep convolution neural networks) to image data measured by DPQR on 30 samples to classify particles in biosimilar products produced under different stress conditions. Approaches should be able to differentiate particles from different stress types, the product, and container closure system.
- Apply supervised and unsupervised machine learning approaches (e.g. deep convolution neural networks) to image data measured by DPQR on 30 samples to characterize particles in biosimilars via images taken with Backgrounded Membrane Imaging techniques. Approaches should account for the optical properties of the particles (e.g. reflective, transparent) and morphology (e.g. high deviation from circularity)
- Combine computational statistics and neural network-based metric learning to characterize heterogeneous suspensions of subvisible particles (those <100 microns) in biologics.
- Apply AI characterization techniques to Flow Imaging and Backgrounded Membrane Imaging data from biosimilar drug products
- Combine computational statistics and neural network-based metric learning to characterize and predict potential root cause of particle formation in biosimilar drug products
- Demonstrable experience and prior publications in applying supervised and unsupervised machine learning approaches to classify visible and subvisible particle images in biologics
- Experience in analyzing image data of visible and subvisible particles and devising approaches to compensate for optical phenomenon at different length scales
- Prior expertise in working with pharmaceutical industry, regulatory authorities, and academic institutions
- Knowledge of typical imaging techniques applied to drug product characterization such as micro flow imaging and digital optical microscopy

## Personnel

- The service shall provide at least (1) trained scientist to apply machine learning approaches to analysis image data for particle classification.

## Deliverables

- Report on analysis of classifying particles in biosimilar products produced under different stress conditions
- Report on analysis of classifying particles in complex drug products.

- Training provided to DPQR staff on application of AI/ML for particle classification and interpretation of results from AI particle classification approaches for product quality analysis

### **Delivery Location**

U.S. Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Testing and Research  
Attention: Maxwell Korang-Yeboah  
10903 New Hampshire Ave  
Silver spring, MD 20904

### **Period of Performance**

Base Period: September 12, 2023 to September 11, 2024

## **CONTRACT ADMINISTRATION**

### **Contracting Officer's Representative (COR):**

Maxwell Korang-Yeboah  
Phone: 301-796-0041  
Email: [Maxwell.Korang-Yeboah@fda.hhs.gov](mailto:Maxwell.Korang-Yeboah@fda.hhs.gov)

The contact information for the FDA Contracting Officer is the following:

Ian Weiss  
U.S. Food and Drug Administration  
Office of Acquisitions and Grants Services  
4041 Powder Mill Road, 5<sup>th</sup> floor  
Beltsville, MD 20705  
Email: [Ian.Weiss@fda.hhs.gov](mailto:Ian.Weiss@fda.hhs.gov)  
Telephone: (301)796-5782

**The Contracting Officer is the only person with authority to act as agent of the Government under this contract.** Only the Contracting Officer has authority to direct or negotiate any changes in the order, including modifying or extending the period of performance, changing the delivery schedule, and authorizing reimbursement to the Contractor for any costs incurred during the performance of their contracts.

The contact information for the FDA Contract Specialist is the following:

Sheila Brown  
U.S. Food and Drug Administration

Office of Acquisitions and Grants Services  
 4041 Powder Mill Road, 5<sup>th</sup> floor  
 Beltsville, MD 20705  
 Telephone: (301) 796-0827  
 Email: [Sheila.Brown1@fda.hhs.gov](mailto:Sheila.Brown1@fda.hhs.gov).

## **CONTRACT CLAUSES**

### **HHSAR Clauses Incorporated by Reference**

This order incorporates the following U.S. Department of Health and Human Services Acquisition Regulation (HHSAR) clauses by reference with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at the following website:

<http://www.hhs.gov/policies/hhsar/>.

<u>HHSAR Clause</u>	<u>Description</u>	<u>Date</u>
352.203-70	Anti-lobbying	(Dec 2015)
352.215-70	Late proposals and revisions	(Dec 2015)
352.223-70	Safety and health	(Dec2015)
352.224-70	Privacy Act	(Dec 2015)
352.233-71	Litigation and claims	(Dec 2015)

### **52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)**

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at:

[www.acquisition.gov/far/index.html](http://www.acquisition.gov/far/index.html)

52.202-1 Definitions (June 2020)

52.203-5 Covenant Against Contingent Fees (May 2014)

52.203-7 Anti-Kickback Procedures (June 2020)

52.212-4 Contract Terms and Conditions-Commercial Items (Dec 2022)

52.233-4 Applicable Law for Breach of Contract Claim (Oct 2004)

### **52.212-5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Products and Commercial Services (JUN 2023)**

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial products and commercial services:

(1) [52.203-19](#), Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further

Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) [52.204-23](#), Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (NOV 2021) (Section 1634 of Pub. L. 115-91).

(3) [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (NOV 2021) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) [52.209-10](#), Prohibition on Contracting with Inverted Domestic Corporations (NOV 2015).

(5) [52.232-40](#), Providing Accelerated Payments to Small Business Subcontractors (MAR 2023) ([31 U.S.C. 3903](#) and [10 U.S.C. 3801](#)).

(6) [52.233-3](#), Protest After Award (AUG 1996) ([31 U.S.C. 3553](#)).

(7) [52.233-4](#), Applicable Law for Breach of Contract Claim (OCT 2004) (Public Laws 108-77 and 108-78 ([19 U.S.C. 3805 note](#))).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial products and commercial services:

*[Contracting Officer check as appropriate.]*

(1) [52.203-6](#), Restrictions on Subcontractor Sales to the Government (JUN 2020), with *Alternate I* (NOV 2021) ([41 U.S.C. 4704](#) and [10 U.S.C. 4655](#)).

(2) [52.203-13](#), Contractor Code of Business Ethics and Conduct (NOV 2021) ([41 U.S.C. 3509](#))).

(3) [52.203-15](#), Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (JUN 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

(4) [52.204-10](#), Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020) (Pub. L. 109-282) ([31 U.S.C. 6101 note](#)).

(5) [Reserved].

(6) [52.204-14](#), Service Contract Reporting Requirements (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).

\_\_ (7) [52.204-15](#), Service Contract Reporting Requirements for Indefinite-Delivery Contracts (OCT2016) (Pub. L. 111-117, section 743 of Div. C).

X (8) [52.204-27](#), Prohibition on a ByteDance Covered Application (JUN2023) (Section 102 of Division R of Pub. L. 117-328).

X (9) [52.209-6](#), Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (NOV 2021) ([31 U.S.C. 6101 note](#)).

\_\_ (10) [52.209-9](#), Updates of Publicly Available Information Regarding Responsibility Matters (OCT2018) ([41 U.S.C. 2313](#)).

\_\_ (11) [Reserved].

\_\_ (12) [52.219-3](#), Notice of HUBZone Set-Aside or Sole-Source Award (OCT2022) ([15 U.S.C. 657a](#)).

\_\_ (13) [52.219-4](#), Notice of Price Evaluation Preference for HUBZone Small Business Concerns (OCT2022) (if the offeror elects to waive the preference, it shall so indicate in its offer) ([15 U.S.C. 657a](#)).

\_\_ (14) [Reserved]

\_\_ (15)

(i) [52.219-6](#), Notice of Total Small Business Set-Aside (NOV 2020) ([15 U.S.C. 644](#)).

\_\_ (ii) Alternate I (MAR 2020) of [52.219-6](#).

\_\_ (16)

(i) [52.219-7](#), Notice of Partial Small Business Set-Aside (NOV 2020) ([15 U.S.C. 644](#)).

\_\_ (ii) Alternate I (MAR 2020) of [52.219-7](#).

\_\_ (17) [52.219-8](#), Utilization of Small Business Concerns (OCT2022) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)).

\_\_ (18)

(i) [52.219-9](#), Small Business Subcontracting Plan (OCT2022) ([15 U.S.C. 637\(d\)\(4\)](#)).

\_\_ (ii) Alternate I (NOV 2016) of [52.219-9](#).

- (iii) Alternate II (NOV 2016) of [52.219-9](#).
- (iv) Alternate III (JUN 2020) of [52.219-9](#).
- (v) Alternate IV (SEP 2021) of [52.219-9](#).
- (19)
  - (i) [52.219-13](#), Notice of Set-Aside of Orders (MAR 2020) ( [15 U.S.C. 644\(r\)](#)).
  - (ii) Alternate I (MAR 2020) of [52.219-13](#).
- (20) [52.219-14](#), Limitations on Subcontracting (OCT 2022) ( [15 U.S.C. 637s](#)).
- (21) [52.219-16](#), Liquidated Damages—Subcontracting Plan (SEP 2021) ( [15 U.S.C. 637\(d\)\(4\)\(F\)\(i\)](#)).
- (22) [52.219-27](#), Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (OCT 2022) ( [15 U.S.C. 657f](#)).
- (23)
  - (i) [52.219-28](#), Post Award Small Business Program Rerepresentation (MAR 2023)( [15 U.S.C. 632\(a\)\(2\)](#)).
  - (ii) Alternate I (MAR 2020) of [52.219-28](#).
- (24) [52.219-29](#), Notice of Set-Aside for, or Sole-Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (OCT 2022) ( [15 U.S.C. 637\(m\)](#)).
- (25) [52.219-30](#), Notice of Set-Aside for, or Sole-Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (OCT 2022) ( [15 U.S.C. 637\(m\)](#)).
- (26) [52.219-32](#), Orders Issued Directly Under Small Business Reserves (MAR 2020) ( [15 U.S.C. 644\(r\)](#)).
- (27) [52.219-33](#), Nonmanufacturer Rule (SEP 2021) ( [15U.S.C. 637\(a\)\(17\)](#)).
- (28) [52.222-3](#), Convict Labor (JUN 2003) (E.O.11755).
- (29) [52.222-19](#), Child Labor-Cooperation with Authorities and Remedies (DEC 2022) (E.O.13126).
- (30) [52.222-21](#), Prohibition of Segregated Facilities (APR 2015).

\_\_ (31)

X(i) [52.222-26](#), Equal Opportunity (SEP 2016) (E.O.11246).

\_\_ (ii) Alternate I (FEB 1999) of [52.222-26](#).

\_X\_ (32) (i) [52.222-35](#), Equal Opportunity for Veterans (JUN 2020) ( [38 U.S.C. 4212](#)).

\_\_ (ii) Alternate I (JUL 2014) of [52.222-35](#).

\_X\_ (33) (i) [52.222-36](#), Equal Opportunity for Workers with Disabilities (JUN 2020) ( [29 U.S.C. 793](#)).

\_\_ (ii) Alternate I (JUL 2014) of [52.222-36](#).

\_\_ (34) [52.222-37](#), Employment Reports on Veterans (JUN 2020) ( [38 U.S.C. 4212](#)).

\_\_ (35) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496).

\_\_ (36)

(i) [52.222-50](#), Combating Trafficking in Persons (NOV 2021) ( [22 U.S.C. chapter 78](#) and E.O. 13627).

\_\_ (ii) Alternate I (MAR 2015) of [52.222-50](#) ( [22 U.S.C. chapter 78](#) and E.O. 13627).

\_\_ (37) [52.222-54](#), Employment Eligibility Verification (MAY 2022) (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial products or commercial services as prescribed in FAR [22.1803](#).)

\_\_ (38)

(i) [52.223-9](#), Estimate of Percentage of Recovered Material Content for EPA– Designated Items (May 2008) ( [42 U.S.C. 6962\(c\)\(3\)\(A\)\(ii\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

\_\_ (ii) Alternate I (MAY 2008) of [52.223-9](#) ( [42 U.S.C. 6962\(i\)\(2\)\(C\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

\_\_ (39) [52.223-11](#), Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).

\_\_ (40) [52.223-12](#), Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (JUN 2016) (E.O. 13693).



\_\_ (41)

(i) [52.223-13](#), Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).

\_\_ (ii) Alternate I (OCT 2015) of [52.223-13](#).

\_\_ (42)

(i) [52.223-14](#), Acquisition of EPEAT®-Registered Televisions (JUN2014) (E.O.s 13423 and 13514).

\_\_ (ii) Alternate I (Jun2014) of [52.223-14](#).

\_\_ (43) [52.223-15](#), Energy Efficiency in Energy-Consuming Products (MAY 2020) ( [42 U.S.C. 8259b](#)).

\_\_ (44)

(i) [52.223-16](#), Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).

\_\_ (ii) Alternate I (JUN 2014) of [52.223-16](#).

\_\_ (45) [52.223-18](#), Encouraging Contractor Policies to Ban Text Messaging While Driving (JUN 2020) (E.O. 13513).

\_\_ (46) [52.223-20](#), Aerosols (JUN2016) (E.O. 13693).

\_\_ (47) [52.223-21](#), Foams (Jun2016) (E.O. 13693).

\_\_ (48) (i) [52.224-3](#) Privacy Training (JAN 2017) (5 U.S.C. 552 a).

\_\_ (ii) Alternate I (JAN 2017) of [52.224-3](#).

\_X\_ (49) (i) [52.225-1](#), Buy American-Supplies (OCT2022) ( [41 U.S.C. chapter 83](#)).

\_\_ (ii) Alternate I (OCT 2022) of [52.225-1](#).

\_\_ (50) (i) [52.225-3](#), Buy American-Free Trade Agreements-Israeli Trade Act (DEC 2022) ( [19 U.S.C. 3301 note](#), [19 U.S.C. 2112 note](#), [19 U.S.C. 3805 note](#), [19 U.S.C. 4001 note](#), 19 U.S.C. chapter 29 (sections 4501-4732), Public Law 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

\_\_ (ii) Alternate I [Reserved].

- \_\_\_ (iii) Alternate II (DEC 2022) of [52.225-3](#).
- \_\_\_ (iv) Alternate III (JAN 2021) of [52.225-3](#).
- \_\_\_ (v) Alternate IV (Oct 2022) of [52.225-3](#).
- \_\_\_ (51) [52.225-5](#), Trade Agreements (DEC 2022) ( [19 U.S.C. 2501](#), *et seq.*, [19 U.S.C. 3301](#) note).
- \_\_\_ (52) [52.225-13](#), Restrictions on Certain Foreign Purchases (FEB 2021) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
- \_\_\_ (53) [52.225-26](#), Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. Subtitle A, Part V, Subpart G Note).
- \_\_\_ (54) [52.226-4](#), Notice of Disaster or Emergency Area Set-Aside (Nov 2007) ( [42 U.S.C. 5150](#)).
- \_\_\_ (55) [52.226-5](#), Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) ( [42 U.S.C. 5150](#)).
- \_\_\_ (56) [52.229-12](#), Tax on Certain Foreign Procurements (FEB 2021).
- \_\_\_ (57) [52.232-29](#), Terms for Financing of Purchases of Commercial Products and Commercial Services (NOV 2021) ( [41 U.S.C. 4505](#), [10 U.S.C. 3805](#)).
- \_\_\_ (58) [52.232-30](#), Installment Payments for Commercial Products and Commercial Services (NOV 2021) ( [41 U.S.C. 4505](#), [10 U.S.C. 3805](#)).
- \_\_X\_ (59) [52.232-33](#), Payment by Electronic Funds Transfer-System for Award Management (OCT2018) ( [31 U.S.C. 3332](#)).
- \_\_\_ (60) [52.232-34](#), Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) ( [31 U.S.C. 3332](#)).
- \_\_X\_ (61) [52.232-36](#), Payment by Third Party (MAY 2014) ( [31 U.S.C. 3332](#)).
- \_\_\_ (62) [52.239-1](#), Privacy or Security Safeguards (AUG 1996) ( [5 U.S.C. 552a](#)).
- \_\_\_ (63) [52.242-5](#), Payments to Small Business Subcontractors (JAN 2017) ( [15 U.S.C. 637\(d\)\(13\)](#)).
- \_\_\_ (64)

(i) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (NOV 2021) ( [46 U.S.C. 55305](#) and [10 U.S.C. 2631](#)).

\_\_\_ (ii) Alternate I (APR 2003) of [52.247-64](#).

\_\_\_ (iii) Alternate II (NOV 2021) of [52.247-64](#).

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial products and commercial services:

[Contracting Officer check as appropriate.]

\_\_\_ (1) [52.222-41](#), Service Contract Labor Standards (AUG2018) ( [41 U.S.C. chapter67](#)).

\_\_\_ (2) [52.222-42](#), Statement of Equivalent Rates for Federal Hires (MAY 2014) ( [29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).

\_\_\_ (3) [52.222-43](#), Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (AUG 2018) ( [29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).

\_\_\_ (4) [52.222-44](#), Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) ( [29U.S.C.206](#) and [41 U.S.C. chapter 67](#)).

\_\_\_ (5) [52.222-51](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) ( [41 U.S.C. chapter 67](#)).

\_\_\_ (6) [52.222-53](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (MAY 2014) ( [41 U.S.C. chapter 67](#)).

\_\_\_ (7) [52.222-55](#), Minimum Wages for Contractor Workers Under Executive Order 14026 (JAN 2022).

\_\_\_ (8) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (JAN 2022) (E.O. 13706).

\_\_\_ (9) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) ( [42 U.S.C. 1792](#)).

(d) *Comptroller General Examination of Record*. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR [2.101](#), on the date of award of this contract, and does not contain the clause at [52.215-2](#), Audit and Records-Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart [4.7](#), Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)

(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1), in a subcontract for commercial products or commercial services. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

(i) [52.203-13](#), Contractor Code of Business Ethics and Conduct (NOV 2021) ([41 U.S.C. 3509](#)).

(ii) [52.203-19](#), Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) [52.204-23](#), Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (NOV 2021) (Section 1634 of Pub. L. 115-91).

(iv) [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (NOV 2021) (Section 889(a)(1)(A) of Pub. L. 115-232).

(v) [52.204-27](#), Prohibition on a ByteDance Covered Application (JUN 2023) (Section 102 of Division R of Pub. L. 117-328).

(vi) [52.219-8](#), Utilization of Small Business Concerns (OCT 2022) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)), in all subcontracts that offer further subcontracting opportunities.

If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR [19.702\(a\)](#) on the date of subcontract award, the subcontractor must include [52.219-8](#) in lower tier subcontracts that offer subcontracting opportunities.

- (vii) [52.222-21](#), Prohibition of Segregated Facilities (APR 2015).
- (viii) [52.222-26](#), Equal Opportunity (SEP 2015) (E.O.11246).
- (ix) [52.222-35](#), Equal Opportunity for Veterans (JUN2020) ( [38 U.S.C. 4212](#)).
- (x) [52.222-36](#), Equal Opportunity for Workers with Disabilities (JUN 2020) ( [29 U.S.C. 793](#)).
- (xi) [52.222-37](#), Employment Reports on Veterans (JUN 2020) ( [38 U.S.C. 4212](#)).
- (xii) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause [52.222-40](#).
- (xiii) [52.222-41](#), Service Contract Labor Standards (AUG 2018) ( [41 U.S.C. chapter 67](#)).
- (xiv)
  - (A) [52.222-50](#), Combating Trafficking in Persons (NOV 2021) ( [22 U.S.C. chapter 78](#) and E.O 13627).
  - (B) Alternate I (MAR 2015) of [52.222-50](#) ( [22 U.S.C. chapter 78](#) and [E.O. 13627](#)).
- (xv) [52.222-51](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) ( [41 U.S.C. chapter 67](#)).
- (xvi) [52.222-53](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (MAY 2014) ( [41 U.S.C. chapter 67](#)).
- (xvii) [52.222-54](#), Employment Eligibility Verification (MAY 2022) (E.O. 12989).
- (xviii) [52.222-55](#), Minimum Wages for Contractor Workers Under Executive Order 14026 (JAN 2022).
- (xix) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (JAN 2022) (E.O. 13706).
- (xx)

(A) [52.224-3](#), Privacy Training (Jan 2017) ( [5 U.S.C. 552a](#)).

(B) Alternate I (JAN 2017) of [52.224-3](#).

(xxi) [52.225-26](#), Contractors Performing Private Security Functions Outside the United States (OCT 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. Subtitle A, Part V, Subpart G Note).

(xxii) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (JUN 2020) ( [42 U.S.C. 1792](#)). Flow down required in accordance with paragraph (e) of FAR clause [52.226-6](#).

(xxiii) [52.232-40](#), Providing Accelerated Payments to Small Business Subcontractors (Mar 2023) ( [31 U.S.C. 3903](#) and [10 U.S.C. 3801](#)). Flow down required in accordance with paragraph (c) of [52.232-40](#).

(xxiv) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (NOV 2021) ( [46 U.S.C. 55305](#) and [10 U.S.C. 2631](#)). Flow down required in accordance with paragraph (d) of FAR clause [52.247-64](#).

(2) While not required, the Contractor may include in its subcontracts for commercial products and commercial services a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

*Alternate I* (FEB 2000). As prescribed in [12.301](#) (b)(4)(i), delete paragraph (d) from the basic clause, redesignate paragraph (e) as paragraph (d), and revise the reference to "paragraphs (a), (b), (c), or (d) of this clause" in the redesignated paragraph (d) to read "paragraphs (a), (b), and (c) of this clause".

*Alternate II* (JUN 2023). As prescribed in [12.301](#) (b)(4)(ii), substitute the following paragraphs (d)(1) and (e)(1) for paragraphs (d)(1) and (e)(1) of the basic clause as follows:

(d)(1) The Comptroller General of the United States, an appropriate Inspector General appointed under section 3 or 8 G of the Inspector General Act of 1978 ( [5 U.S.C. App.](#) ), or an authorized representative of either of the foregoing officials shall have access to and right to—

(i) Examine any of the Contractor's or any subcontractors' records that pertain to, and involve transactions relating to, this contract; and

(ii) Interview any officer or employee regarding such transactions.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), and (c), of this clause, the Contractor is not required to flow down any FAR clause in a subcontract for commercial products or commercial services, other than—

(i) *Paragraph (d) of this clause.* This paragraph flows down to all subcontracts, except the authority of the Inspector General under paragraph (d)(1)(ii) does not flow down; and

(ii) *Those clauses listed in this paragraph (e)(1).* Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

(A) [52.203-13](#), Contractor Code of Business Ethics and Conduct (NOV 2021) ([41 U.S.C. 3509](#)).

(B) [52.203-15](#), Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009 (JUN 2010) (Section 1553 of Pub. L. 111-5).

(C) [52.204-23](#), Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (NOV 2021) (Section 1634 of Pub. L. 115-91).

(D) [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (NOV 2021) (Section 889(a)(1)(A) of Pub. L. 115-232).

(E) [52.204-27](#), Prohibition on a ByteDance Covered Application (JUN 2023) (Section 102 of Division R of Pub. L. 117-328).

(F) [52.219-8](#), Utilization of Small Business Concerns (OCT 2022) ([15 U.S.C. 637\(d\)\(2\) and \(3\)](#)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR [19.702\(a\)](#) on the date of subcontract award, the subcontractor must include [52.219-8](#) in lower tier subcontracts that offer subcontracting opportunities.

(G) [52.222-21](#), Prohibition of Segregated Facilities (APR 2015).

(H) [52.222-26](#), Equal Opportunity (SEP 2016) (E.O. 11246).

(I) [52.222-35](#), Equal Opportunity for Veterans (JUN 2020) ([38 U.S.C. 4212](#)).

(J) [52.222-36](#), Equal Opportunity for Workers with Disabilities (JUN 2020) ([29 U.S.C. 793](#)).

(K) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause [52.222-40](#).

(L) [52.222-41](#), Service Contract Labor Standards (AUG 2018) ([41 U.S.C. chapter 67](#)).

(M) \_\_\_ (1) [52.222-50](#), Combating Trafficking in Persons (NOV 2021) ( [22 U.S.C. chapter 78](#) and E.O 13627).

\_\_\_ (2) Alternate I (MAR 2015) of [52.222-50](#) ( [22 U.S.C. chapter 78](#) and [E.O. 13627](#)).

(N) [52.222-51](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) ( [41 U.S.C. chapter 67](#)).

(O) [52.222-53](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (MAY 2014) ( [41 U.S.C. chapter 67](#)).

(P) [52.222-54](#), Employment Eligibility Verification (MAY 2022) (Executive Order 12989).

(Q) [52.222-55](#), Minimum Wages for Contractor Workers Under Executive Order 14026 (JAN 2022).

(R) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (JAN 2022) (E.O. 13706).

(S) \_\_\_ (1) [52.224-3](#), Privacy Training (JAN 2017) ( [5 U.S.C. 552a](#)).

\_\_\_ (2) Alternate I (JAN 2017) of [52.224-3](#).

(T) [52.225-26](#), Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. Subtitle A, Part V, Subpart G Note).

(U) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations. (JUN 2020) ( [42 U.S.C. 1792](#)). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(V) [52.232-40](#), Providing Accelerated Payments to Small Business Subcontractors (MAR 2023) ( [31 U.S.C. 3903](#) and [10 U.S.C. 3801](#)). Flow down required in accordance with paragraph (c) of [52.232-40](#).

(W) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (NOV 2021) ( [46 U.S.C. 55305](#) and [10 U.S.C. 2631](#)). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

#### **52.204-27 Prohibition on a ByteDance Covered Application.**

As prescribed in [4.2203](#)(c), insert the following clause:



PROHIBITION ON A BYTEDANCE COVERED APPLICATION (JUN 2023)

(a) *Definitions.* As used in this clause—

*Covered application* means the social networking service TikTok or any successor application or service developed or provided by ByteDance Limited or an entity owned by ByteDance Limited.

*Information technology*, as defined in 40 U.S.C. 11101(6)—

(1) Means any equipment or interconnected system or subsystem of equipment, used in the automatic acquisition, storage, analysis, evaluation, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information by the executive agency, if the equipment is used by the executive agency directly or is used by a contractor under a contract with the executive agency that requires the use—

(i) Of that equipment; or

(ii) Of that equipment to a significant extent in the performance of a service or the furnishing of a product;

(2) Includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources; but

(3) Does not include any equipment acquired by a Federal contractor incidental to a Federal contract.

(b) *Prohibition.* Section 102 of Division R of the Consolidated Appropriations Act, 2023 (Pub. L. 117-328), the No TikTok on Government Devices Act, and its implementing guidance under Office of Management and Budget (OMB) Memorandum M-23-13, dated February 27, 2023, “No TikTok on Government Devices” Implementation Guidance, collectively prohibit the presence or use of a covered application on executive agency information technology, including certain equipment used by Federal contractors. The Contractor is prohibited from having or using a covered application on any information technology owned or managed by the Government, or on any information technology used or provided by the Contractor under this contract, including equipment provided by the Contractor’s employees; however, this prohibition does not apply if the Contracting Officer provides written notification to the Contractor that an exception has been granted in accordance with OMB Memorandum M-23-13.

(c) *Subcontracts.* The Contractor shall insert the substance of this clause, including this paragraph (c), in all subcontracts, including subcontracts for the acquisition of commercial products or commercial services.

(End of clause)

1. The following clauses are incorporated into the contract:
  - a. **352.232-71 Electronic Submission of Payment Requests (FEB 2022)**

(a) Definitions. As used in this clause—

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), “Content of Invoices” and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at [www.ipp.gov](http://www.ipp.gov) or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(END OF CLAUSE)

**b. FDA Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP) (Jan 2022)**

- a) All Invoice submissions for goods and or services must be made electronically through the U.S. Department of Treasury’s Invoice Processing Platform System (IPP). <http://www.ipp.gov/vendors/index.htm>
- b) Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in in FAR 32.905(b), “Content of Invoices” and the applicable Payment clause included in this contract, or the clause 52.212-4 Contract Terms and Conditions – Commercial Items included in commercial items contracts. The IPP website address is: <https://www.ipp.gov>.
- c) (1) The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 – 5 business days of the contract award for new contracts or date of modification for existing contracts.  
  
(2) Registration emails are sent via email from [ipp.noreply@mail.eroctwai.gov](mailto:ipp.noreply@mail.eroctwai.gov). Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to [IPPCustomerSupport@fiscal.treasury.gov](mailto:IPPCustomerSupport@fiscal.treasury.gov) or phone (866) 973-3131.  
(3) The Contractor POC will receive two emails from **IPP Customer Support**, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.  
(4) If your company is already registered to use IPP, you will not be required to re-register.  
(5) If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.
  - a. Invoices that include time and materials or labor hours Line Items must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).
  - b. Invoices that include cost-reimbursement Line Items must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts.

At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.

- Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;

- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
  - Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
  - Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
  - Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
  - Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
  - Fee – amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.
- c. Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:
- (a) list of all invoices submitted to date under the subject award, including the following:
    - (1) invoice number, amount, & date submitted
    - (2) corresponding payment amount & date received
  - (b) total amount of all payments received to date under the subject contract or order
  - (c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance.
- g. Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.
- h. If the services are rejected for failure to conform to the technical requirements of the task order, or any other contractually legitimate reason, the Contractor shall not be paid, or shall be paid an amount negotiated by the CO.
- i. Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.
- j. The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.

k. Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at [ERIC@fda.hhs.gov](mailto:ERIC@fda.hhs.gov). Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.  
(END OF CLAUSE)

## **INSTRUCTIONS TO THE OFFEROR**

### **RESPONSE DATES**

Offers in response to this solicitation shall be due no later than Wednesday, August 23, 2023, 3:30PM Eastern Standard Time and must be emailed to [Sheila.Brown1@fda.hhs.gov](mailto:Sheila.Brown1@fda.hhs.gov). Questions are due no later than Monday, August 21, 2023, by 3:30 pm and must be emailed to [Sheila.Brown1@fda.hhs.gov](mailto:Sheila.Brown1@fda.hhs.gov).

### **Instructions**

Note: The Government reserves the right to evaluate quotes and make awards without discussions. Therefore, the Offeror's initial proposal shall contain the Offeror's best terms from a cost/price and technical standpoint. However, the Government may conduct discussions if the Contracting Officer determines they are necessary. Offeror are requested to demonstrate their expertise through a written quote. Quotes shall be separated into two (2) Volumes (Volume 1 – Technical Quotation, Volume 2 – Business Quotation as shown in the following table:

Please submit the following information for FDA's review:

#### **Volume 1: Technical Quotation**

1) The Contractor shall provide their overall technical understanding/approach to this requirement.

The Contractor shall submit the documents in both unlocked PDF and Word/Excel formats. FDA will evaluate the quotation to ensure that it is responsive and technically acceptable, that the proposed prices are fair and reasonable.

#### **Volume 2: Business Quotation**

- 1) This order will be firm-fixed-price
- 2) Provide a price build-up for this requirement by completing the pricing schedule.
- 3) Proposed pricing shall NOT be subject to change during the 12-month base period of

performance.

*FDA is not responsible for any costs incurred in preparing a quotation responding to this Request for Quotation.*

### **BASIS FOR AWARD**

The Government will award a firm-fixed price (FFP) order resulting from this solicitation that represents the best value to the Government., technical, price, and other factors considered. In addition to price, the Government will evaluate the extent to which the offeror's quote demonstrates the quality of their approach for executing for what is described in the Statement of Work. The FDA will also evaluate the fairness and price reasonableness of the total proposed pricing submitted.