



August 3, 2023

SUBJECT: Request for Quote (RFQ-118941-75F40123Q00433) for Purchase of Cryopreserved Hepatocytes

This is a combined synopsis/solicitation for commercial services prepared in accordance with the format in FAR 12.6 as supplemented with FAR 13 and additional information included in this notice. The incorporated provisions and clauses are those in effect through Federal Acquisition Circular (FAC) 2023-04.

THIS ANNOUNCEMENT CONSTITUTES THE ONLY SOLICITATION AND A SEPARATE SOLICITATION WILL NOT BE ISSUED.

The solicitation number for this acquisition is RFQ-118941-75F40123Q00433 and is being issued as a Request for Quote (RFQ). The NAICS Code for this solicitation: 334516. The requirement will be awarded as Firm-Fixed Price and 100% small business set-aside. The Government reserves the right to award without discussions if the Contracting Officer determines that the initial offer is providing the Best Value and discussions are not necessary.

*****Brand Name or Equal Buy*****

Background:

The Division of Applied Regulatory Science (DARS) OCP/OTS/CDER is conducting a research program to evaluate the usefulness of hepatocytes in liver MPS for regulatory purposes. As part of this process DARS needs to acquire cryopreserved hepatocytes to conduct further research and evaluate the usefulness of the liver MPS.

For successful engraftment to occur the following quality characteristics have been experimentally demonstrated to be essential:

- A minimum of 5 x 10⁶ cells per vial
- Shall be able to be plated and induction qualified

In addition to above, FDA will perform lot testing across as many lots as possible in order to identify which lot gives the best results.

The Contractor shall provide up to a total of 17 vials of cryopreserved human hepatocytes (liver cells) from 3 donors

The Contractor shall provide human hepatocytes (liver cells) with at least 100 million hepatocytes from each donor.

1) Technical Requirements:

The Offeror shall indicate if the minimum salient characteristics have been met to be considered responsive for this requirement.



Technical Requirements:

- 1.1 Full (anonymous) donors' information available and provided
- 1.2 A total of 3 different donors will be required.
 - A) Age
 - B) Sex
 - C) Race/ethnicity
 - D) Cause of death
 - E) Tobacco/Alcohol or Substance abuse history
 - F) Disclosure of serious medical conditions affecting the liver (e.g. cirrhosis)
- 1.3 Tested negative for HIV, Hepatitis (B/C)
- 1.4 Testing results available for CMV and EBV
- 1.5 Shall be from a single donor (not pooled)
- 1.6 Shall have minimum viability post-thaw of 85%
- 1.7 Shall be induction qualified
- 1.8 Shall be able to be plated
- 1.9 **Summary of Items:**

Description	Part/Product #	Quantity
Female Human Cryoplateable Hepatocytes, Spheroid Certified, 5 million LOT AZG	F00995-SCERT	5
Female Human Cryoplateable Hepatocytes, Spheroid Certified, 5 million LOT IIN	F00995-SCERT	6
Male Human Cryoplateable Hepatocytes, Spheroid Certified, 5 million LOT IIQ	M00995-SCERT	6

- 1.10 Other Considerations:



- A) **Site Preparation Information:** Contractor shall include any, and all site-preparation information required for proper system operation and maintenance, including physical space, ventilation, and IT/network requirements, if applicable.
- B) **Warranty:**
Items shall be warranted for 12 months from the date of acceptance. Warranty shall include all parts, labor, unlimited travel, and technical support.

2) **Delivery Requirements**

The Contractor shall deliver (s) in this purchase order as follows:

- A) The quantities ordered within 60 days of order award, no later than October 31, 2023.
- B) All deliverables required under this order shall be packaged, marked and shipped in accordance with Government specifications.
- C) At a minimum, all deliverables shall be marked with the order number and contractor's name. The Contractor shall guarantee that all required materials shall be delivered in immediate new, usable and acceptable condition.
- D) Contractor shall contact TPOC to schedule the delivery within 30 days of award. Delivery hours are 08:00 am – 3:00 pm, Monday – Thursday EDT, excluding Federal holidays and weekends. Contractor shall provide tracking number and shipment notification so that FDA is notified of shipment.

The Contractor shall be responsible for shipment at the US Food and Drug Administration (FDA) facility address listed below:

The items need to be delivered to the TPOC at:

US FDA,
Attn: TBD
10903 New Hampshire Ave
Bldg 64 rm 2010;
Silver Spring, MD 20993

- E) The contractor is responsible for ensuring the shipment is made under appropriate conditions (such as liquid nitrogen or dry ice)
- F) Deliveries must be coordinated with the Project Officer prior to shipment. No deliveries will be accepted without prior authorization from the Project Officer.

3) **Period of Performance:**

- A) The Contractor shall deliver the order within 7 days of award. The warranty period shall be 12 months from date of FDA acceptance.



4) **Place of Performance:**

10903 New Hampshire Ave
Bldg 64 rm 2010;
Silver Spring, MD 20993

5) **Inspection and Acceptance:**

The Technical Point of Contact (TPOC), shall perform inspection and acceptance within 30 days after shipment.

Inspection: FOB Destination

6) **GOVERNMENT HOLIDAYS**

a. The Government hereby provides notification that Government personnel observe the listed days as holidays:

- | | |
|--|-----------------------|
| (1) New Year's Day | (7) Labor Day |
| (2) Martin Luther King's Birthday | (8) Columbus Day |
| (3) President's Day | (9) Veterans' Day |
| (4) Memorial Day | (10) Thanksgiving Day |
| (5) Juneteenth National Independence Day | (11) Christmas Day |
| (6) Independence Day | |

b. In addition to the days designated as holidays, the Government observes the following days:

- (1) Any other day designated by Federal Statute
- (2) Any other day designated by Executive Order
- (3) Any other day designated by the President's Proclamation

c. When any such day falls on a Saturday, the following Monday is observed. Except for designated around-the-clock or emergency operations, Contractor personnel will not be able to perform on-site under this contract with FDA on holidays set forth above. The Contractor will not charge any holiday as direct charge to the award.

d. It is understood and agreed between the Government and the Contractor that observance of such days by Government personnel shall not otherwise be a reason for an additional period of performance, or entitlement of compensation except as set forth within the award.

e. Nothing in this clause abrogates the rights and responsibilities of the parties relating to stop work provisions as cited in other sections of this contract.



7) Invoicing Procedures:

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 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. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to 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.
- d. 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).
- e. 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.

1. 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;
2. Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
3. Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
4. 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;
5. Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
6. Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
7. Fee - amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

f. 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:

HHSAR 352.211-3 Paperwork Reduction Act

HHSAR 352.222-70 Contractor Cooperation in Equal Employment Opportunity Investigations

HHSAR 352.239-74 Electronic and Information Technology Accessibility

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

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 (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

(8) 52.204-27, Prohibition on a ByteDance Covered Application (Jun 2023) (Section 102 of Division R of Pub. L. 117-328).

(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 (Oct 2018) (41 U.S.C. 2313).

(11) [Reserved].



- (12) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (Oct 2022) (15 U.S.C. 657a).
- (13) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Oct 2022) (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 (Oct 2022) (15 U.S.C. 637(d)(2) and (3)).
- (18) (i) 52.219-9, Small Business Subcontracting Plan (Oct 2022) (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) (i) 52.222-26, Equal Opportunity (Sep 2016) (E.O.11246).
- (ii) Alternate I (Feb 1999) of 52.222-26.
- (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.



- (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 (Jun 2014) (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 (Jun 2016) (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.
- (49) (i) 52.225-1, Buy American-Supplies (Oct 2022) (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).
 - (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).
 - ___ (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:
- ___ (1) 52.222-41, Service Contract Labor Standards (Aug 2018) (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 (Jun 2020) (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).
- (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.

FAR clause 52.217-8 Option to Extend Services (Nov 1999).

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within at any time.

PROVISIONS:

1. FAR 52.252-2 Solicitation Provisions 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 this/these address(es): <https://www.acquisition.gov/far> and <https://www.acquisition.gov/hhsar>.



2. FAR 52.212-2 Evaluation-Commercial Items (Nov 2021)
3. FAR 52.212-3 Offeror Representations and Certifications-Commercial Items (Mar 2022)
Offerors that fail to complete the required representations and certifications, or reject the terms and conditions of the solicitation, may be excluded from award consideration.

The offeror shall complete only paragraphs (b) of this provision if the Offeror has completed the annual representations and certification electronically via the System for Award Management (SAM) Web site accessed through <http://www.acquisition.gov> . If the Offeror has not completed the annual representations and certifications electronically, the Offeror shall complete only paragraphs (c) through (p) of this provision.

8) Pricing Schedule:

The Offeror shall submit a fixed price, including details of all costs supporting the price for the requested items/services.

The Offeror shall complete the pricing chart below. Pricing shall include all applicable fees including shipping, warranty and handling. Any charges presented after contract award shall not be acceptable.

Line	Description	Part/Product #	Qty.	Unit Price	Price
1	Female Human Cryoplateable Hepatocytes, Spheroid Certified, 5 million LOT AZG	F00995-SCERT	5 EA	\$	\$
2	Female Human Cryoplateable Hepatocytes, Spheroid Certified, 5 million LOT IIN	F00995-SCERT	6 EA	\$	\$
3	Male Human Cryoplateable Hepatocytes, Spheroid Certified, 5 million LOT IIQ	M00995-SCERT	6 EA	\$	\$
4	Shipping & Handling		1	\$	\$
GRAND TOTAL FIXED PRICE (All Items FOB)					\$

Pricing should be outlined as shown above.



NOTE: ONLY ONE PRICE SUMMARY REPORT AND AGREGATE TOTAL WILL BE CONSIDERED FOR EVALUATION/AWARD WITH ALL PROPOSED PRICING ASSOCIATED WITH THE RFQ REQUIREMENTS. NO ADDITIONAL PRICING SCHEDULES WILL BE EVALUATED BY THE GOVERNMENT.

- a) The Contractor's quotation shall include: All items requested or none.
- b) Contractors are required to fill in the above pricing table
- c) Contractor shall show any pricing related to labor hours, materials associated with providing design, delivery and installation (as applicable).
- d) Contractors shall submit a complete schedule of prices and a single summary total amount shall be furnished for the entire requirement.
- e) **The Contractor's current address, Unique Identity ID shall be included in the quote.**
- f) The quotation shall contain sufficient information to allow the Government to perform a basic analysis of the proposed price of the work.

9) **EVALUATION AND AWARD:**

Lowest Priced, Technically Acceptable (LPTA)

10) **INSTRUCTION TO CONTRACTORS:**

11.1 The Contractor shall complete the Pricing Schedule above.

11.2 Deadline for questions: August 7, 2023 at 11:00 AM Eastern Time, no phone calls will be accepted. Email questions to: sarah.hussain@fda.hhs.gov

11.3 **Offer due date/local time: August 11, 2023, at 11:00 AM Eastern Time. Email quotes to sarah.hussain@fda.hhs.gov**

11.4 **Quote submission format:**

Quote shall be in 2 volumes: 1st volume shall be Technical and 2nd volume shall be Price. The volumes shall be separate and complete. The volumes shall be separate and complete, so that evaluation of one may be accomplished independently of, and concurrently with, the evaluation of the other. No pricing information shall be provided in volume 1.

The total number of pages for the technical quote shall not exceed ten (10) pages, using 1" margins, single spaced, font type Time New Roman, and a font size of 12.

***The solicitation does not commit the Government to pay any cost for the preparation and submission of a quote or proposal. It is also advised that the Contracting Officer (CO) is the only individual who can legally commit and obligate the



Government to the expenditure of public funds in connection with the proposed acquisition.***

CONTRACTING POINT OF CONTACT:

Sarah Hussain, Contract Specialist
 4041 Powder Mill Road
 Beltsville, MD 20705
 Email: sarah.hussain@fda.hhs.gov

FAR 52.252-1 Solicitation Provisions Incorporated by Reference (Feb 1998).

This solicitation incorporates one or more solicitation provisions 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. The offeror is cautioned that the listed provisions may include blocks that shall be completed by the offeror and submitted with the proposal. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with the proposal. Also, the full text of a solicitation provision may be accessed electronically at this address: www.acquisition.gov/far/index.html.

FAR 52.225-2 Buy American Certificate. (OCT 2022)

or certifies that each end product, except those listed in paragraph (b) of this provision, is a domestic end product and that each domestic end product listed in paragraph (c) of this provision contains a critical component.

(2) The Offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products. For those foreign end products that do not consist wholly or predominantly of iron or steel or a combination of both, the Offeror shall also indicate whether these foreign end products exceed 55 percent domestic content, except for those that are COTS items. If the percentage of the domestic content is unknown, select "no".

(3) The Offeror shall separately list the line item numbers of domestic end products that contain a critical component (see FAR 25.105).

(b) Foreign End Products:

(4) The terms "commercially available off-the-shelf (COTS) item," "critical component," "domestic end product," "end product," and "foreign end product" are defined in the clause of this solicitation entitled "Buy American-Supplies."

Line Item No.	Country of Origin	Exceeds 55% domestic Content (yes/no)
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[List as necessary]

(c) Domestic end products containing a critical component:

Line Item No. ____

[List as necessary]

(d) The Government will evaluate offers in accordance with the policies and procedures of part 25 of the Federal Acquisition Regulation.

FAR 52.211-6 Brand Name or Equal (Aug 1999)