RFP-FDA-21-(1238584)

TITLE: DOSE-FINDING STUDY OF KRATOM ALKALOIDS PILOT

INTRODUCTION

The U.S. Food and Drug Administration (FDA), an agency of the Department of Health and Human Services (HHS), is charged with protecting the public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, biological products, and medical devices; ensuring the safety of foods, cosmetics, and radiation-emitting products; and regulating tobacco products.

As part of FDA, the Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines. For example, fluoride toothpaste, antiperspirants, dandruff shampoos and sunscreens are all considered "drugs."

The CDER Office of the Center Director (OCD) provides leadership and overall direction to all CDER activities to ensure that the mission of the Center is accomplished. CDER makes sure that safe and effective drugs are available to improve the health of consumers. CDER ensures that prescription and over-the-counter drugs, both brand name and generic, work correctly and that the health benefits outweigh known risks. The Controlled Substance Staff (CSS) focuses on the assessment of abuse potential of drugs, to promote the public health through the medical science-based assessment and management of drug abuse risks.

NOTICE OF COMBINED SYNOPSIS/SOLICITATION

This is a combined synopsis/solicitation for commercial items prepared in accordance with (IAW) the format in FAR Subpart 12.6, as supplemented with additional information included in this notice. This announcement constitutes the only solicitation; proposals are being requested and a written solicitation will not be issued. This is a request for proposal (RFP) for commercial items IAW the procedures of FAR Part 12 – Acquisition of Commercial Items, in conjunction with FAR Part 15 – Contracting by Negotiation.

NOTICE OF FAC

This solicitation document incorporates provisions and clauses in effect through Federal Acquisition Circular FAC 2021-03, effective February 16, 2021.

NOTICE OF NAICS/SET ASIDE

This requirement is intended for full and open competition. The associated North American Industry Classification System (NAICS) codes are: 541715 (Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology

and Biotechnology)), 541710 (Research and Development in the Physical, Engineering, and Life Sciences), 541990 (All other Professional, Scientific, and Technical Services), 541711 (Research and Development in Biotechnology (except Nanobiotechnology)), and 541720, (Research and Development in the Social Sciences and Humanities). Offerors must have an active registration in SAM.gov (https://beta.sam.gov), with completed representations and certifications, by the close date of the solicitation. Proposals submitted by offerors not registered in SAM.gov will not be considered.

BACKGROUND

FDA has previously warned consumers about the use of Kratom (Mitragyna speciosa), a plant endogenous to Southeast Asia. Kratom has both affinity and activity at mu opioid receptors, receptor sites known to be associated with abuse. Although Kratom use is prevalent, to date, clinical evaluations of abuse potential have not been performed. FDA desires to initiate a pilot, dose finding and human abuse potential (HAP) study of botanical Kratom.

Currently there are limited safety and Chemical, Manufacturing, and Control (CMC) data to support clinical research with botanical kratom and kratom alkaloids. FDA desires to further investigate techniques and protocols with an initial Kratom HAP to help characterize its abuse potential and support future research efforts.

OBJECTIVES

FDA has a requirement for a pilot clinical study to gather the necessary data to characterize the abuse potential of botanical Kratom which may inform future clinical studies of Kratom, mitragynine, and 7-OH-MG, the primary psychoactive constituents of Kratom. These data sets are to include safety information and chemistry manufacturing and controls data (i.e., information to support an Investigational New Drug (IND) Application).

In addition, the data will inform dose selection, statistical analyses, and primary outcome measures for future clinical studies of botanical Kratom and its alkaloids.

PRICE SCHEDULE

CLIN	DESCRIPTION	PRICE
1	Dose-Finding Study Of Kratom Alkaloids Pilot	**$**
2	HAP Study (Part 2) (Optional)	**$**

3	Study Reports (Part 2) (Optional	**$**
TOTAL COST		**$**

SCOPE

Independently and not as an agent of FDA, the Contractor shall furnish the necessary personnel, materials, services, facilities, and otherwise conduct all activities necessary for, or incident to the performance and completion of the HAP study described in this statement of work (SOW).

The purpose of this HAP study is to characterize the abuse potential of botanical Kratom and generate adequate safety information to support an IND for future clinical investigations of Kratom and its primary alkaloids mitragynine and 7-OH-MG.

ASSUMPTIONS/CONSTRAINTS

The Contractor shall be responsible for all aspects of provisioning and safeguarding human subjects for the human abuse potential (HAP) study, including Institutional Review Board (IRB) review and approval. As a consequence, the Contractor shall plan accordingly so as to not adversely impact the timeline for clinical research protocol(s) review and approval.

The Contractor shall designate a Principal Investigator and adhere to FDA Policies and Guidance in the performance of such duties.

FDA has unlimited rights to all documents/material produced under this contract. All documents and materials produced under this contract shall be FDA-owned and are the property of FDA with all rights and privileges of the ownership/copyright belonging exclusively to FDA. These documents and materials may not be used or sold by the Contractor without written permission from the Contracting Officer. All materials supplied to FDA shall be the sole property of FDA and may not be used for any other purpose. All data collected by the Contractor or provided to the Contractor in the performance of this contract are the property of FDA. FDA retains all rights to the data used and all derivative works developed by the Contractor.

REQUIREMENTS

The Contractor shall conduct the requirements of a two (2) part human abuse potential study on botanical Kratom as described in subsequent sections:

The first part (Part 1) comprises of generating adequate data to demonstrate the safe clinical use of botanical Kratom and support an IND application. The Contractor shall perform a thorough literature review and produce the appropriate safety and toxicology information to support an IND for a subsequent HAP study. This will be done using available data and consultation with key opinion leaders familiar with kratom pharmacology and toxicology. During submission of the Investigational New Drug (IND) Application, the Contractor shall determine the appropriate doses of botanical Kratom and its preparation—in consultation with and approved by FDA—to administer to human subjects. Safety (e.g., vital signs) and abuse-related outcome measures (e.g., VAS measures of "liking") will be assessed to inform dosing parameters for future clinical studies.

During the second part (Part 2), the proposed clinical study will examine the abuse liability of botanical Kratom including its subjective effects. The study design will be informed by the guidance for industry "Assessment of Abuse Potential of Drugs," available at: https://www.fda.gov/media/116739/download. The number of doses of Kratom and number of subjects shall be determined by the Investigator in consultation with FDA. The Investigator shall also define the subject inclusion/exclusion criteria (e.g., recreational opioid users that have used botanical Kratom at least once in the past 30 days for its reinforcing effects or "to get high"). Outcome measures shall include ratings (e.g., Emax) of "liking" on a visual analog scale and other subjective and pharmacodynamic effects (e.g., vital signs, and measures of impairment). Exploratory measures of relative reinforcing effects may also be proposed by the Contractor (e.g., choice procedures and/or drug vs. money questionnaires).

Kratom Preparations (Part 1)

The Contractor shall obtain and/or prepare botanical Kratom preparations suitable for oral human administration (e.g., made into a tea or encapsulated). The description of this preparation shall include the Chemistry, Manufacturing, and Control information for: (1) drug substance; (2) drug product; (3) placebo formulation (4) labeling information for the labeled products relevant to the investigational drug; and (5) an environmental analysis for assessment of the effects of the investigational new drug or biological product on the environment. The preparation shall adhere to current FDA guidance and additional information can be found at the following links: https://www.fda.gov/media/70827/download and https://www.fda.gov/regulatory-information/search-fda-guidance-documents/botanical-drug-development-guidance-

industry

The Contractor shall deliver the Kratom preparations suitable for oral human administration within 260-business days after award.

Investigational New Drug (IND) Application (Part 1)
The Contractor shall prepare a draft IND application, as well as prepare and submit a final IND application that conforms to 21 Code of Federal Regulations (CFR) Section 312 and the above guidances. This task includes conducting a preliminary meeting to discuss IND requirements and the Investigator's plan within 30-business days after the Kick-Off Meeting.

The Contractor shall deliver the draft IND application within 120-business days after award. The Contractor shall deliver the final IND application based on a timeframe agreed upon with the COR or designee.

The Contractor shall deliver the IND submission to FDA within 5-business days of receipt of FDA comments on the final IND application.

Clinical Research Protocols (Part 1)

The Contractor shall prepare and submit clinical research protocol(s), including statistical considerations for a HAP study of botanical Kratom in human volunteers. The protocols shall be drafted in conjunction with FDA. Draft and final versions of the clinical study protocol shall be delivered by the Contractor 60- and 90-business days after contract award, respectively. The clinical study protocol documentation shall include the human subjects' protection documentation (e.g., consent form), data analysis plan, data handling and record keeping, quality assurance plan, and administrative information.

The Contractor shall schedule and attend a preliminary meeting to discuss clinical protocol design within 30-business days after the Kick-Off Meeting.

The Contractor shall obtain human subject protection considerations and IRB approvals. The package shall be submitted to IRB for approval within 95 days after contract award.

The Contractor shall respond to queries, clarifications, or provide additional documentation on the submitted package from the IRB, as required.

The Contractor shall inquire, anticipate and assist in obtaining OMB clearances and any Interagency Agreements (IAAs) in coordination with FDA.

HAP Study (Part 2) (Option)

The Contractor shall perform and document research to evaluate the subjective and physiological effects of at least 3-doses of botanical Kratom using a within-subject design in human volunteers (e.g., n=~40 completers). Positive control comparators and a placebo arm will be included in the HAP. The justification and number of doses to be examined shall be provided by the Contractor and determined in consultation with FDA. Pilot studies may be necessary to inform dosing parameters for the HAP study.

Subject recruitment shall be performed by the Contractor, including the development of recruitment materials, and choice of recruitment method (e.g., newspaper or television advertisements). The Contractor shall manage all aspects of recruitment including efforts to retain subjects and increase recruitment.

The Contractor shall deliver the HAP study within 650-business days after award or 390-business days after FDA exercises the option for continuance, whichever is less.

Study Reports (Part 2) (Option)

The Contractor shall perform descriptive and statistical analyses of all clinical data. The Contractor shall also develop and deliver a Study Report that includes the following:

a) Background and purpose of the project
b) Botanical Kratom CMC analyses
c) Clinical data analysis, including statistical analyses
d) Significant problems encountered during the study and their solutions,
e) Data preparation and processing procedures.

The Contractor shall write draft and final study reports fully describing and characterizing the data as described below. Study reports should include detailed accounts of the study procedures (e.g., materials and methods) and be drafted in a format suitable for publication in a peer reviewed scientific journal.

The Contractor shall deliver a Preliminary Study Report to the Contracting Officers Representative (COR) within 740-business days after award or 430 business days after FDA exercises the option for continuance, whichever is less. All raw data and data analysis files will be submitted in SAS transport format and Microsoft Excel, or an appropriate alternative format determined in consultation with FDA.

The Contractor shall deliver a Final Study Report to the COR containing all data generated from the study, including data to support the IND within 780-business days after award or 520 days after FDA exercises the option for continuance, whichever is less. Data files shall be prepared and delivered according to the following specifications:

a) Delivered electronically in SAS transport format and Microsoft Excel
b) Each record shall be uniquely identified and shall correspond to one respondent's data

c) All data values shall be numeric rather than character
d) Adverse events description with the time in the event table
e) One (1) electronic copy of a finalized, complete, and correct Coding Book
f) One (1) electronic copy of the data analyses report, including files, tables and figures, and
appropriate statistical analyses of the results.

PROJECT MANAGEMENT SUPPORT

The Contractor shall perform project management activities. The Contractor shall manage cost, schedule, and quality daily. All management activities for the contract shall be performed throughout the period of performance.

The Contractor shall:

- Ensure that the scope, schedule, performance, and cost are consistent with the terms of the contract.
- Perform full project lifecycle ownership
- Plan and organize work to deliver required results, provide appropriate resources with the required skill and ability to complete the work within agreed upon timeframes, and provide guidance and leadership to those resources.
- Develop a Work Plan.
- Conduct regular project meetings to brief FDA on progress, review issues, updates to the project schedule, and address questions/issues.
    - Provide a monthly status report.
- Monitor contract compliance
- Coordinate all required on-boarding and off-boarding activities including the following:
    - HHS ID Badge Request Form (HHS-745)
    - E-QIP Initiation Form
    - Standard Form 85 or 85P
    - Commitment to Protect Non-Public Information (FDA 3398 Form)
    - User account requests (FORM FDA 3530)
    - Security Awareness Training
    - Submit new or replacement personnel resumes to the Contracting Officer Representative (COR) for review. The COR will verify that the new personnel meet the requirements of the proposed Labor Category and Statement of Work (SOW) before the candidate starts the FDA on-boarding process.
    - Provide the COR with a minimum of thirty (30) days' notice prior to a change to a designated Key Personnel resource due to reassignment. The Contractor shall provide the COR with the resume of the Key Personnel candidate for review and approval before the candidate starts the FDA on-boarding process.

- Coordinate all required Contractor staff training. This includes FDA mandated training courses such as, FDA Records Management Training, Computer Security Awareness Training, and IT Security Recertification.

MEETINGS

The Contractor shall support routine project management and status meetings (e.g. monthly progress meetings, bi-weekly (i.e., every other week) status meetings, ad hoc meetings). The Contractor shall participate in meetings in different capacities, to include leading discussions, contributing questions and answers, raising issues/concerns, recommending potential solutions, developing and giving presentations, and other active oral and written communications. The Contractor shall prepare and track meeting agendas, minutes/notes, issues, and action items for all meetings held with Subject Matter Experts (SMEs) and FDA designated staff in support of the project and any planned deliverable. Meeting minutes shall be required for all project meetings, and shall include participant information, summary of the meeting discussion, action items, issues, and decisions made during meetings.

In addition to the routine project meetings, the Contractor shall schedule and conduct a presentation of its approach at a Kickoff Meeting, to be held within five (5) business days of contract award. The Contractor shall deliver a Summary within three (3) business days after the Kickoff Meeting, to document key decisions, actions, milestones, issues, and concerns that were discussed and agreed upon during the Kickoff Meeting.

REPORTING

The Contractor shall immediately and proactively inform the COR, Project Manager(s) and/or designee(s) of all issues, problems, and recommendations that should be addressed for the overall effective accomplishment of project goals. Upon the COR's approval, recommendations for actions that need to be taken by FDA staff, or other Contractors, shall be clearly defined and will be reviewed by the COR for approval. The Contractor shall communicate each approved action to the responsible party and the FDA, and each approved action shall have identified dates for completion.

Meeting Agendas and Minutes/Notes

The Contractor shall participate in a bi-weekly (i.e., every other week) call with the COR and other FDA staff, as needed. The Contractor shall also participate in other, ad hoc meetings. These calls shall be used as a mechanism for discussing and managing administrative and project issues that surface prior to the call. The Contractor shall produce and deliver agenda items at least two (2) business days prior to the calls and provide a written summary of the teleconference on the third business day following the

meeting. The summary report shall include:

- Date, time and place of meeting;
- Attendees by name and title; and
- Subjects/issues discussed, resolution reached, and action items required

Monthly Status Reports

The Contractor shall submit to the COR a monthly status report, covering all requirements and tasks specified in this SOW, on the 10th business day of each month. Within the first thirty (30) days after contract award, the Contractor shall propose a reporting format, subject to FDA approval. The report shall outline all work accomplished the previous month with a comparison of planned tasks versus actual completion, success in meeting service level metrics (if applicable), and recommendations for changes or additional activities to ensure the tasks support progress on the overall objectives. The report shall also inform the FDA of any significant problems that may adversely affect project performance, cost, risks and the Contractor's proposed solution for addressing these problems.

Project Management Closure Report

The Contractor shall prepare and submit draft and final versions of a comprehensive Project Management Closure Report, 15 business days before-, and the last day of the contract, respectively. The Report shall capture; cost invoice status, summary of work delivered, and any uncompleted activities during the period of performance. The Contractor shall also support FDA in any transition-out activities that may apply to project closure.

Work Plan

The Contractor shall develop a Work Plan that provides the technical approach, organizational resources, deliverables, documentation, and management controls to be employed to meet the cost, performance, and schedule requirements throughout project execution. The Work Plan should represent the formal road map for project activities that communicates a set of goals, processes, and actions by which personnel can accomplish those goals. The Work Plan should also clearly articulate the required steps needed to achieve a stated goal by setting demonstrable objectives and measurable deliverables that can be transformed into actions. The Work Plan shall serve as a guiding document for the Contractor, enabling the realization of an outcome through efficient team activities.

At a minimum, the Work Plan shall address the following areas: Requirements Management, Risk Management, Schedule Management, Cost Management, Quality Management, Communications, Staffing (including plans for Staff Training and Staff Retention) and Project Organization, Performance Metrics, timely delivery and reporting

quality controls, and clearly defined roles, responsibilities, lines of authority, resources appropriately aligned to services and deliverables. Changes to the Work Plan shall be subject to review and approval by the COR. Once approved, the updated Work Plan shall be enforced for implementation of the tasks.

The Contractor shall deliver the Draft Work Plan and Final Work Plan 15- and 25-business days after award.

DELIVERABLES

Format of Deliverables

All deliverables shall be submitted to the Contracting Officer's Representative (COR) and FDA program official as draft at a minimum of five (5) business days before the final deliverable due date. Deliverables (both draft and final versions) shall be provided in soft copy using Microsoft (MS) Office products unless otherwise specified. Summary documents shall be presented in an MS PowerPoint format to easily share with FDA leadership. Daily, weekly, interim, informal, and working-copy products may be provided by email to the COR and FDA program officials. Final soft copies of deliverables, at the end of the period of performance, shall be developed using the current FDA version of MS Office products and/or other standard application software unless otherwise specified.

Deliverable Submission Procedures

The Contractor shall submit the draft and final deliverable to the COR, unless otherwise stated in the deliverable schedule. The COR will be responsible for the review and acceptance of all draft and final deliverables to ensure accuracy, functionality, completeness, professional quality, and overall compliance with the statement of work requirements of the task.

The Contractor shall ensure the accuracy and completeness of all deliverables in accordance with referenced policy, regulations, laws, and directives. Reports and presentations shall be concise and clearly written; errors, misleading or unclear statements, incomplete or irrelevant information, and/or excessive rhetoric, repetition, and "padding," or excessive length if a page limit is imposed, shall be considered deficiencies and will be subject to correction by the Contractor at no additional cost to the government.

A COR will utilize the Contracting Performance Assessment System (CPARS) to assess the contractor's performance based on feedback at task completion. The COR will monitor technical progress including the surveillance and assessment of performance and compliance with project tasks. The COR will perform technical inspections and acceptance of deliverables. The COR will review invoices and facilitate any required corrections.

In the event FDA rejects any deliverable, the COR shall notify the Contractor in writing explaining the specific reason(s) for the rejection. If FDA suggests changes, or rejects, the Contractor shall resubmit the revised deliverable within five (5) business days after receiving FDA's input.

DELIVERABLE SCHEDULE

The list below summarizes specific tasks, activities, and deliverables the Contractor shall deliver in support of FDA objectives. A suggested timeframe for deliverables is included. The Contractor may propose a schedule in their response to the RFP. The final deliverable schedule will be agreed upon the by the Contractor and COR, and will be specified in the Work Plan. Due dates are expressed in business days (versus calendar days).

Deliverable	Description	Due Date	Format
1	Project Kickoff Presentation Briefing	Within 5 days after award	PowerPoint
2	Kickoff Meeting Summary	Within 3 days after Project Kickoff Meeting	Microsoft Word
3	Draft Work Plan	Within 15 days after award	Microsoft Word
4	Final Work Plan	Within 25 days after award	Microsoft Word
	Part 1		
5	Botanical Kratom Preparations Suitable for Oral Human Administration	Within 260 days after award	Microsoft Word
6	Draft IND Application	Within 120 days after award	Microsoft Word
7	Final IND Application	As agreed upon with the COR or designee	Microsoft Word
8	IND submission to FDA	Within 5 days of receipt of FDA comments on Final IND Application	Microsoft Word
9	Draft Clinical Study Protocol	Within 60 days after award	Microsoft Word
10	Final Clinical Study Protocol	Within 90 days after award	Microsoft Word
11	Package submitted to IRB	Within 95 days after award	Microsoft Word
	Part 2		
12	HAP Study (Option)	Within 650 days after award or 390 days after exercising the option, whichever is less	Microsoft Word
13	Preliminary Study	Within 740 days after award or	Microsoft Word

Deliverable	Description	Due Date	Format
	Report (Option)	430 days after exercising the option, whichever is less	
14	Final Study Report (Option)	Within 780 days after award or 520 days after exercising the option, whichever is less	SAS transport format and Microsoft Excel
Additional Project Management Support Deliverables			
15	Meeting Agendas	At least 2 days prior to meetings	Microsoft Word
16	Meeting Minutes/Notes	Within 3 days after meetings	Microsoft Word
17	Monthly Status Report	Proposed template due no later than 30 days after award; monthly reports due the 10th day of each month	Microsoft Word
18	Draft Project Management Closure Report	Within 15 days of project completion	Microsoft Word
19	Final Project Management Closure Report	Last day of period of performance	Microsoft Word

PERIOD OF PERFORMANCE

TBD at time of award.

PLACE OF PERFORMANCE

This contract shall be performed at the Contractor's facility, to include laboratory requirements. The Contractor shall be responsible for any subcontracted work.

TRAVEL

Travel encountered by the Contractor in the performance of the service(s) shall not be re-imbursed.

KEY PERSONNEL

The Key Personnel specified for this contract are essential to work performance. Pursuant to HHSAR Clause 352.237-75, Key Personnel (December 2015), the Key Personnel for this contract are identified below.

The Contractor shall ensure that all Key Personnel are on-board immediately following contract award. The Contractor shall ensure that Contractor personnel have initiated background checks immediately after award.

Labor Category	Description
Senior Scientist/Principal Investigator: Human Abuse Potential Study design and operation	Extensive knowledge of human abuse potential (HAP) study design and methodology, including statistical considerations. Experience with the overall management and conduct of HAP studies including budgeting and project management.

GOVERNMENT-FURNISHED PROPERTY, MATERIAL, EQUIPMENT, OR INFORMATION

No Government-furnished property will be provided to the Contractor. During protocol development, FDA personnel will be available to consult with the Contractor and provide feedback. This feedback will be provided via regular (e.g., biweekly) meetings or as needed.

INVOICING PROCEDURES

FDA Three-Way Match Invoicing Procedures

A. The Contractor shall submit all invoices to:
U.S. FOOD AND DRUG ADMINISTRATION
Attn: Vendor Payments
Division of Payment Services
10903 New Hampshire Ave
WO32 - Second Floor
MAIL HUB 2145
Silver Spring, MD 20993-0002
301-827-3742
FDAVendorPaymentsTeam@fda.hhs.gov

*** Acceptable methods of delivery include: E-mail (preferred) and Standard Mail. Provide a copy marked courtesy to the COR.

B. Invoices submitted under this contract must comply with the requirements set forth in FAR Clauses 52.232-25 (Prompt Payment) and 52.232-33 (Payment by Electronic Funds Transfer – System for Award Management) and/or other applicable FAR clauses specified herein. To constitute a proper invoice, the invoice must be submitted on company letterhead and include each of the following:
(i) Name and address of the contractor;
(ii) Invoice date and invoice number;
(iii) Contract/Order number (including a reference to any base award for Indefinite-Delivery/Indefinite-Quantity Contracts or Blanket Purchase Agreements);

(iv) Description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed, including:
(a) period of performance for which costs are claimed;
(b) itemized travel costs, including origin and destination;
(c) any other supporting information necessary to clarify questionable expenditures;
(d) the contractor shall include the Contract Line Item/Funding line item for each description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed;
(v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on government bill of lading;
(vi) Terms of any discount for prompt payment offered (Prompt Payment terms other than NET 30);
(vii) Name and address of official to whom payment is to be sent (must be the same as that in the purchase order/award, or in a proper notice of assignment)
(viii) Name, title, and phone number of person to notify in event of defective invoice;
(ix) Taxpayer Identification Number (TIN);
(x) Banking routing transit number of the financial institution receiving payment for Electronic funds transfer (EFT);
(xi) Name and telephone number of the FDA Contracting Officer Representative (COR) or other Program Center/Office point of contact, as referenced on the award;
(xii) For all Inspections, Time-and-Materials and Labor-Hour Awards, 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;
(xiii) Any other information or documentation required by the award.

C. An electronic invoice is acceptable if submitted in adobe acrobat (PDF) format. All items listed in (i) through (xiii) of this clause must be included in the electronic invoice. Electronic invoices must be on company letterhead and must contain no ink changes and be legible for printing.

D. Questions regarding invoice payments should be directed to the 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. 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.

CONTRACT ADMINISTRATION

The Contracting Officer's Representative (COR) will perform inspection and acceptance of equipment, installation and services to be provided.

The COR is responsible for the following as required by this order: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluations; (4) performing technical inspections and acceptances; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the ***only person with authority to act as an agent of the Government under this order***. 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, authorizing reimbursement to the Contractor for any costs incurred during the performance of this order, or otherwise change any terms and conditions of this order.

The contact information for the FDA Contracting Officer's Representative is: TBD

The contact information for the FDA Contracting Officer is: TBD

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

The contact information for the contractor is: TBD

CONTRACT TYPE

The contract type will be Fixed-Price.

SECURITY

1) Applicability. The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes either or both of the following:
   a) Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.
   b) Operate a Federal System Containing Information: A Contractor (and/or any subcontractor) will operate a federal system and information technology containing data that supports the HHS mission. In addition to the Federal

Acquisition Regulation (FAR) Subpart 2.1 definition of "information technology" (IT), the term as used in this section 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.

2) Safeguarding Information and Information Systems. In accordance with the Federal Information Processing Standards Publication (FIPS)199, Standards for Security Categorization of Federal Information and Information Systems, the Contractor (and/or any subcontractor) shall:

a) Protect government information and information systems in order to ensure:

Confidentiality, which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;

Integrity, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and

Availability, which means ensuring timely and reliable access to and use of information. Provide security for any Contractor systems, and information contained therein, connected to an FDA network or operated by the Contractor on behalf of FDA regardless of location. In addition, if new or unanticipated threats or hazards are discovered by either the agency or contractor, or if existing safeguards have ceased to function, the discoverer shall immediately, within one (1) hour or less, bring the situation to the attention of the other party. This includes notifying the FDA Systems Management Center (SMC) within one (1) hour of discovery/detection in the event of an information security incident.

b) Adopt and implement the policies, procedures, controls, and standards required by the HHS/FDA Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the FDA Information Security Program security requirements, outlined in the FDA Information Security and Privacy Policy (IS2P), by contacting the CO/COR or emailing your ISSO.

c) Comply with the Privacy Act requirements and tailor FAR clauses as needed.

3) Information Security Categorization. In accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-60, Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories, Appendix C, and based on information provided by

the ISSO or other security representative, the risk level for each Security Objective and the Overall Risk Level, which is the highest watermark of the three factors (Confidentiality, Integrity, and Availability) of the information or information system are the following:

Confidentiality: [ ] Low [ ] Moderate [ ] High
Integrity: [ ] Low [ ] Moderate [ ] High
Availability: [ ] Low [ ] Moderate [ ] High
Overall Risk Level: [ ] Low [ ] Moderate [ ] High

Based on information provided by the Privacy Office, system/data owner, or other privacy representative, it has been determined that this solicitation/contract involves:
[X] No PII [ ] Yes PII

Personally Identifiable Information (PII). Per the OMB Circular A-130, "PII is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: Social Security number, date and place of birth, mother's maiden name, biometric records, etc.

PII Confidentiality Impact Level has been determined to be: [✓] Low [ ] Moderate [ ] High

4) Controlled Unclassified Information (CUI). CUI is defined as "information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information." The Contractor (and/or any subcontractor) must comply with Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR, part 2002) when handling CUI. 32 C.F.R. 2002.4(aa). As implemented the term "handling" refers to "…any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information." 81 Fed. Reg. 63323. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, shall be:

   a) marked appropriately;

   b) disclosed to authorized personnel on a Need-To-Know basis;

   c) protected in accordance with NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline if handled by a Contractor system operated on behalf of the agency, or NIST SP 800-171, Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations if handled by internal Contractor system; and returned to FDA control, destroyed when no longer needed, or held until otherwise directed;

d) Destruction of information and/or data shall be accomplished in accordance with NIST SP 800-88, Guidelines for Media Sanitization and the FDA IS2P Appendix T: Sanitization of Computer-Related Storage Media.

5) Protection of Sensitive Information. For security purposes, information is or may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Contractor (and/or any subcontractor) shall protect all government information that is or may be sensitive in accordance with OMB Memorandum M-06-16, Protection of Sensitive Agency Information by securing it with a FIPS 140-2 validated solution.

Confidentiality and Nondisclosure of Information. Any information provided to the Contractor (and/or any subcontractor) by FDA or collected by the Contractor on behalf of FDA shall be used only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any FDA records may be made available or disclosed shall be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.
The confidentiality, integrity, and availability of such information shall be protected in accordance with HHS and FDA policies. Unauthorized disclosure of information will be subject to the HHS/FDA sanction policies and/or governed by the following laws and regulations:

a. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);

b. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and

c. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

6) Internet Protocol Version 6 (IPv6). All procurements using Internet Protocol shall comply with OMB Memorandum M-05-22, Transition Planning for Internet Protocol Version 6 (IPv6).

7) Government Websites. All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent version of Transport Layer Security (TLS). In addition, HTTPS shall enable HTTP Strict Transport Security (HSTS) to instruct compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that attempt to downgrade connections to plain HTTP. For internal-facing websites, the HTTPS is not required, but it is highly recommended.

8) Contract Documentation. The Contractor shall use FDA-provided templates, policies, forms and other agency documents to comply with contract deliverables as appropriate.

9) Standard for Encryption. The Contractor (and/or any subcontractor) shall:

   a) Comply with the HHS Standard for Encryption of Computing Devices and Information to prevent unauthorized access to government information.

   b) Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with FIPS 140-2 validated encryption solution.

   c) All devices (i.e.: desktops, laptops, mobile devices, etc.) that store, transmit, or process non-public FDA information should utilize FDA-provided or FDA information security authorized devices that meet HHS and FDA-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).

   d) Verify that the encryption solutions in use are compliant with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the COR.

   e) Use the Key Management system on the HHS Personal Identification Verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys. Encryption keys (PIV card) shall be provided to the COR upon request and at the conclusion of the contract. Upon completion of contract, contractor ensures that COR is able to access and read any encrypted data.

10) Contractor Non-Disclosure Agreement (NDA). Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract shall complete the FDA non-disclosure agreement (3398 Form), as applicable. A copy of each signed and witnessed NDA shall be submitted to the CO and/or COR prior to performing any work under this acquisition.

11) Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) – The Contractor shall assist the procuring activity representative, program office and the FDA SOP or designee with conducting a PTA for the information system and/or information handled under this contract to determine whether or not a full PIA needs to be completed.

   a) If the results of the PTA show that a full PIA is needed, the Contractor shall assist procuring activity representative, program office and the FDA SOP or designee

with completing a PIA for the system or information after completion of the PTA and in accordance with HHS and FDA policy and OMB M-03-22, Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002. The PTA/PIA must be completed and approved prior to active use and/or collection or processing of PII and is a prerequisite to agency issuance of an ATO.

b) The Contractor shall assist the procuring activity representative, program office and the FDA SOP or designee in reviewing and updating the PIA at least every three years throughout the Enterprise Performance Life Cycle (EPLC) /information lifecycle, or when determined by the agency that a review is required based on a major change to the system, or when new types of PII are collected that introduces new or increased privacy risks, whichever comes first.

SECTION 508 COMPLIANCE

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) requires Federal agencies to purchase electronic and information technologies (EIT) that meet specific accessibility standards. This law helps to ensure that federal employees with disabilities have access to, and use of, the information and data they need to do their jobs. Furthermore, this law ensures that members of the public with disabilities have the ability to access government information and services.

There are three regulations addressing the requirements detailed in Section 508. The Section 508 technical and functional standards are codified at 36 CFR Part 1194 and may be accessed through the Access Board's Web site at http://www.access-board.gov. The second regulation issued to implement Section 508 is the Federal Acquisition Regulation (FAR). FAR Part 39.2 requires that agency acquisitions of Electronic and Information Technology (EIT) comply with the Access Board's standards. The entire FAR is found at Chapter 1 of the Code of Federal Register (CFR) Title 48, located at http://www.acquisition.gov. The FAR rule implementing Section 508 can be found at http://www.section508.gov. The third applicable regulation is the HHS Acquisition Regulation (HHSAR).

Regardless of format, all Web content or communications materials produced for publication on or delivery via HHS Web sites - including text, audio or video - must conform to applicable Section 508 standards to allow federal employees and members of the public with disabilities to access information that is comparable to information provided to persons without disabilities. All contractors (including subcontractors) or consultants responsible for preparing or posting content intended for use on an HHS-funded or HHS-managed Web site must comply with applicable Section 508 accessibility standards, and where applicable, those set forth in the referenced policy or standards documents below. Remediation of any materials that do not comply with the applicable provisions of 36 CFR Part 1194 as set forth in the SOW, shall be the responsibility of the contractor or consultant retained to produce the Web-suitable content or communications material.

Unless an agency exception to this requirement exists, the Contractor must conform to applicable Section 508 standards and must apply best practices associated with Section 508 compliance during the application design, development, and testing phases. The Contractor shall utilize FDA approved tools to verify the compliance with the Section 508 standards and ensure the delivery of the fully compliant products.

The following Sections apply to this procurement:

E101.2 Equivalent Facilitation (Appendix A, Application and Scoping Requirements)
E203 Access to Functionality (Appendix A, Application and Scoping Requirements)
E204 Functional Performance Criteria (Appendix A, Application and Scoping Requirements)
E205 Electronic Content (Appendix A, Application and Scoping Requirements)
302 Functional Performance Criteria (Appendix C, Application and Scoping Requirements)
E208 Support Documentation and Services (Appendix A, Application and Scoping Requirements)
Chapter 6 Support Documentation (Appendix C, Application and Scoping

REQUIREMENTS

Special Material Requirements

There are no requirements for any special materials in the performance of the service(s).

Human Subject Protection Review

For research exempt from the requirements of 45 CFR Part 46:

(a)The Contractor will submit to FDA a letter from their IRB or human subject protection entity that the proposed research is exempt (see 45 CFR 46.104).

(b)In accordance with SMG 9001.4, FDA will follow its procedures for exempt research determination. Data collection from human subjects cannot commence under this contract until the FDA COR provides the Contractor with the outcome of the FDA determination.

For nonexempt human subjects research:

(a) The Contractor agrees to protect the rights and welfare of human subjects involved in research under this contract by complying with 45 CFR Part 46 and the clause at HHSAR 352.270-4b.

(b) Initial proof of compliance with 45 CFR Part 46 shall consist of:
(1) A copy of a current Federal-wide Assurance on file with OHRP (https://www.hhs.gov/ohrp/)

federalwide-assurances-fwas.html). The copy of a current Federal–wide Assurance shall be included with the Contractor's proposal;

(2) A letter from the Contractor's local IRB (the Institutional Review Board (IRB) specified in the Offeror's Assurance of Compliance) stating that it has reviewed and approved the proposed research protocol. The letter from the local IRB shall be submitted to the Contracting Officer Representative (COR).

(3) In accordance with SMG 9001.4, the FDA will determine if FDA is considered engaged in the research for purposes of 45 CFR part 46. Data collection from human subjects cannot commence under this contract until the FDA COR provides the Contractor with the outcome of the FDA determination. When that determination is made, the FDA will confirm the extent to which the terms of "352.270-11 Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required" apply

Compliance with FDA Site-visits:

During the period of performance of this contract, FDA personnel or a vendor on behalf of FDA may conduct site visits. FDA may collect information from the vendor to ensure that the study is conducted, recorded, and reported in compliance with the study protocol, study specific risk-appropriate quality monitoring plans, Standard Operating Procedures, FDA Institutional Review Board (IRB) Policies and Procedures, Good Clinical Practice (GCP) standards (applicable only in clinical studies) and Federal regulation HHS 45 CFR § 46, as well as any additional applicable agency regulatory requirements.

The COR and/or FDA Project Lead will communicate and provide notice to the awardee that a site visit will be conducted at least 15 days in advance of the visit, except in the case of For-Cause site visits, for which FDA personnel or a vendor on behalf of FDA may conduct site visits at any time without advance notification. The awardee shall coordinate with FDA to ensure that FDA has access to all requested information during the site visit. The information collected during the site visit will be provided to FDA for further review and analysis.

PII shall be marked and/or masked as directed by the COR, to protect such information. All work, data, and leveraged systems shall be available for inspection/audit. Further, all work and related data pertaining to this contract shall remain isolated from other projects/work that the contractor is engaged in to facilitate seamless sharing of work and data with the FDA and its duly authorized agents.

All information shall be readily available in a standard, readable format. If information is encrypted, the encryption key shall be made available to the Government. Any special tools, equipment or software necessary to read the information shall be provided to the Government at no additional cost. The contractor shall not invoice for any additional work related to comply with this requirement, absent unusual circumstances. Any such instances shall require the advance approval of the Contracting Officer.

In the event of identified conflicts between this language and clauses in this contract, the clauses shall prevail as to any specific requirements. All other contractor performance requirements stated herein shall still have full force and effect. However, the contractor shall immediately notify the contracting officer upon becoming aware of any such conflict.

CONTRACT CLAUSES

FAR Clauses Incorporated by Reference:

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

52.202-1	Definitions (November 2013)
52.203-5	Covenant Against Contingent Fees (May 2014)
52.203-7	Anti-Kickback Procedures (May 2014)
52.204-24	Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment (Dec 2019)
52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (Aug 2020)
52.204-26	Covered Telecommunication s Equipment or Services Representation (Oct 2020)
52.212-4	Contract Terms and Conditions-Commercial Items (May 2015)
52.227-14	Rights in Data-General (May 2014)
52.232-40	Providing Accelerated Payments to Small Business Subcontractors Continuity of Services (Jan 1991)
52.232-16	Progress Payments (Jun 2020)
52.233-40	Applicable Law for Breach of Contract Claim (Oct 2004)

FAR Clauses in Full Text:

52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OF EXECUTIVE ORDERS—COMMERCIAL ITEMS (DEC 2015)
(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 items:
(1) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015) (2) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C. 3553).
(3) 52.233-4, Applicable Law for Breach of Contract Claim (OCT 2004) (Public Laws 108-
77, 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 items:

__(1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).

__X(2) 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (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).

X (4) 52.204-10, Reporting Executive compensation and First-Tier Subcontract Awards (Oct
2015) (Pub. L. 109-282) (31 U.S.C.
__6101 note). (5) [Reserved]

__X(6) 52.204-14, Service Contract Reporting Requirements (Jan 2014) (Pub. L. 111-117, section 743 of Div. C).

__(7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts
(Jan 2014) (Pub. L. 111-117, section 743 of Div. C).

X (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors
Debarred, Suspended, or Proposed for Debarment (Oct 2015) (31 U.S.C. 6101 note).

__(
(Jul 2013) (41 U.S.C.
__2313). (10)
[Reserved]

__(11) (i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (Nov 2011) (15 U.S.C. 657a).

__(ii) Alternate I (Nov 2011) of 52.219-3.

__(12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Oct 2014) (if the offeror elects to waive the preference, it shall so indicate in its offer)(15 U.S.C. 657a).

__(ii) Alternate I (Jan 2011) of
__52.219-4. (13) [Reserved]

__ (14) (i) 52.219-6, Notice of Total Small Business Aside (Nov 2011) (15 U.S.C.
__644). (ii) Alternate I (Nov 2011).

__(iii) Alternate II (Nov 2011).

__(15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C.
__644). (ii) Alternate I (Oct 1995) of 52.219-7.

__(iii) Alternate II (Mar 2004) of 52.219-7.

__(16) 52.219-8, Utilization of Small Business Concerns (Oct 2014) (15 U.S.C. 637(d)(2) and (3)).

__(17) (i) 52.219-9, Small Business Subcontracting Plan (Oct 2015) (15 U.S.C. 637
__(d)(4)). (ii) Alternate I (Oct 2001) of 52.219-9.

__(iii) Alternate II (Oct 2001) of 52.219-
__9. (iv) Alternate III (Oct 2015) of
52.219-9.
__(18) 52.219-13, Notice of Set-Aside of Orders (Nov 2011) (15 U.S.C. 644(r)).
__X__ (19) 52.219-14, Limitations on Subcontracting (Nov 2011) (15 U.S.C.
__637(a)(14)). (20) 52.219-16, Liquidated Damages—Subcontracting Plan (Jan
1999) (15 U.S.C.
637(d)(4)(F)(i)).
__(21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside
(Nov 2011) (15 U.S.C. 657f).
__ (22) 52.219-28, Post Award Small Business Program Rerepresentation (Jul 2013) (15
U.S.C.
632(a)(2)).

__(23) 52.219-29, Notice of Set-Aside for Economically Disadvantaged Women-Owned
Small Business (EDWOSB) Concerns (Jul 2013) (15 U.S.C. 637(m)).
__(24) 52.219-30, Notice of Set-Aside for Women-Owned Small Business
(WOSB) Concerns Eligible Under the WOSB Program (Jul 2013) (15 U.S.C.
637(m)).
__X__ (25) 52.222-3, Convict Labor (June 2003) (E.O. 11755).
__X__ (26) 52.222-19, Child Labor—Cooperation with Authorities and Remedies (Jan 2014)
(E.O.
13126).
__X__ (27) 52.222-21, Prohibition of Segregated Facilities (Apr
2015). __X__ (28) 52.222-26, Equal Opportunity (Apr 2015)
(E.O. 11246).
__X__ (29) 52.222-35, Equal Opportunity for Veterans (Oct 2015) (38 U.S.C. 4212).
__X__ (30) 52.222-36, Equal Opportunity for Workers with Disabilities (Jul 2014) (29
U.S.C. 793). __X__ (31) 52.222-37, Employment Reports on Veterans (Oct 2015) (38 U.S.C.
4212).
__X__ (32) 52.222-40, Notification of Employee Rights Under the National Labor Relations
Act
(Dec 2010) (E.O. 13496).
__X__ (33) (i) 52.222-50, Combating Trafficking in Persons (Mar 2015) (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).
__X__ (34) 52.222-54, Employment Eligibility Verification (Oct 2015). (E. O. 12989). (Not
applicable to the acquisition of commercially available off-the-shelf items or certain
other types of commercial items as prescribed in 22.1803.)
__(35) (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.)
__(36) (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.
__(37) (i) 52.223-14, Acquisition of EPEAT® -Registered Television (Jun 2014) (E.O.s 13423 and 13514).
__(ii) Alternate I (Jun 2014) of 52.223-14.
__(38) 52.223-15, Energy Efficiency in Energy-Consuming Products (Dec 2007) (42 U.S.C. 8259b).
__(39) (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.
X (40) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging while Driving
(Aug 2011) (E.O. 13513).
X (41) 52.225-1, Buy American--Supplies (May 2014) (41 U.S.C. chapter 83).
X (42) (i) 52.225-3, Buy American--Free Trade Agreements--Israeli Trade Act (May 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19
U.S.C. 4001 note, Pub. L. 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 (May 2014) of
__52.225-3. (iii) Alternate II (May 2014)
__of 52.225-3. (iv) Alternate III (May
2014) of 52.225-3.

X (43) 52.225-5, Trade Agreements (Nov 2013) (19 U.S.C. 2501, *et seq.*, 19 U.S.C. 3301 note).
X (44) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
__(45) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Jul 2013) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
__(46) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150).
__(47) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).
__(48) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505), 10 U.S.C. 2307(f)).
__(49) 52.232-30, Installment Payments for Commercial Items (Oct 1995) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
X (50) 52.232-33, Payment by Electronic Funds Transfer— System for Award Management
(Jul 2013) (31 U.S.C. 3332).
__(51) 52.232-34, Payment by Electronic Funds Transfer—Other Than System for Award

Management (Jul 2013) (31 U.S.C. 3332).
__(52) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).
X (53) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
__(54) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C.
__2631). (ii) Alternate I (Apr 2003) 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 items:

__(1) 52.222-17, Nondisplacement of Qualified Workers (May 2014) (E.O. 13495)
__(2) 52.222-41, Service Contract Labor Standards (May 2014) (41 U.S.C. chapter 67.).
__(3) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
__X(4) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards -- Price Adjustment (Multiple Year and Option Contracts) (May 2014) (29 U.S.C.206 and 41 U.S.C. chapter 67).
__X(5) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards -- Price Adjustment (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
__(6) 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).
__(7) 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).
__(8) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015) (E.O.
__13658). (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (May 2014)
(42 U.S.C. 1792).

(10) 52.237-11, Accepting and Dispensing of $1 Coin (Sep 2008) (31 U.S.C. 5112(p)(1)).

(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, 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 items. 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 (Oct 2015) (41 U.S.C. 3509). (ii) 52.219-8, Utilization of Small Business Concerns (Oct 2014) (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 $700,000 ($1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(iii) 52.222-17, Nondisplacement of Qualified Workers (May 2014) (E.O. 13495). Flow down required in accordance with paragraph (1) of FAR clause 52.222-17.
(iv) 52.222-21, Prohibition of Segregated Facilities (Apr
2015). (v) 52.222-26, Equal Opportunity (Apr 2015)
(E.O. 11246).
(
vi) 52.222-35, Equal Opportunity for Veterans (Oct 2015) (38 U.S.C. 4212).

(vii) 52.222-36, Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C. 793). (viii) 52.222-37, Employment Reports on Veterans (Oct 2015) (38 U.S.C. 4212).
(ix) 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.

(x) 52.222-41, Service Contract Labor Standards (May 2014), (41 U.S.C. chapter 67).
(xi) (A) 52.222-50, Combating Trafficking in Persons (Mar 2015) (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 E.O. 13627).

(xii) 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.)

(xiii) 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) (xiv) 52.222-54, Employment Eligibility Verification (Oct
2015) (E. O. 12989).
(xv) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015) (E.O. 13658).

(xvi) 52.225-26, Contractors Performing Private Security Functions Outside the United States
(Jul 2013) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year
2008; 10 U.S.C. 2302 Note).

(xvii) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (May 2014) (42
U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xviii) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) 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 items a minimal number of additional clauses necessary to satisfy its contractual obligations.

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/.

HHSAR Clause	Description	Date
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)
352.227-70	Publications and Publicity	(Dec 2015)
352.227-71	Confidential Information	(Dec 2015)
352.233-71	Litigation and claims	(Dec 2015)
352.237-75	Key Personnel	(Dec 2015)

INSTRUCTIONS TO OFFERORS

All relevant questions or requests for clarification related to this solicitation shall be submitted using Attachment 2 (RFP Questions Template). Questions submitted without using the Attachment 2 template, and following the instructions provided therein shall not be given consideration. The form shall be submitted electronically to the following email address: the Contract Specialist (Telisha.Wilson@fda.hhs.gov), by no later than 10:00 AM EST, on July 21, 2021. The Government may not consider questions received after this date and time. The email subject line shall read: **FDA-RFP-21-1238584**. It is the Offeror's responsibility to confirm receipt of all proposals and/or questions by the closing date of this announcement by contacting the above Contract Specialist/Contracting Officer.

NOTE: Emails sent to the FDA contact stated in this solicitation shall not exceed 15 MBs (Megabytes) each. Offerors' complete submissions must be received by the by the closing date and time stated above in order to be considered for award. Receipt of offers by FDA at the specified email address by the specified closing date and time is the sole responsibility of the Offeror. The FDA shall not be responsible for late or non-delivery of Offerors' proposals due to IT problems, server or other technical issues. It is strongly recommended that Offerors request confirmation of receipt on any proposal or other submissions to ensure timely receipt by FDA. In order to ensure timely receipt of proposals, Offerors should NOT wait until the last moment to electronically submit quotations. Proposals found to be non-compliant with the instructions of this solicitation shall not be accepted.

Proposal submission due date

The Offeror's proposal shall be received by no later than 10:00 AM EST, on August 09, 2021. Proposals shall be submitted electronically via email to the Contract Specialist (CS) (Telisha.Wilson@fda.hhs.gov), The subject line shall read: **FDA-RFP-21-1238584**. Late submissions may not be evaluated. Fax submissions are NOT authorized.

A complete Proposal shall consist of and be submitted in three parts:

1) Cover Letter;
2) Volume I – Technical Proposal
3) Volume II – Business Proposal

Each part shall be submitted as separate documents and shall be complete so that evaluation of one part may be independent of, and concurrently with, evaluation of another. For submission purposes, it is acceptable for all volumes to be submitted in the same email; however, each attachment must be clearly marked to which volume it belongs to. Each volume shall include a cover sheet which clearly identifies each volume by volume number and volume name (i.e., Volume I - Technical Proposal), solicitation number, and date of submission, and shall include page headers with the same information.

The Offeror shall submit each part in native format (Microsoft (MS) Word, Excel, etc.) or as PDF files, however, MS Word/Excel formats are preferred. Failure to provide the required documents in response to this solicitation may render the offeror's proposal non-responsive.

Cover Letter

Offerors shall include a cover letter that contains, at a minimum, the following information:

- Name of Offeror and Address
- Offeror DUNS number
- Point(s) of Contact – Name, telephone number, and email address
- Business size and type (e.g., small, 8(a) small businesses, HUBZone, etc.)
- Statement that the proposal is valid for 120 days
- Identification of any teaming arrangements, joint ventures, mentor-protégé relationships, subcontracting relationships, etc.
- Signature of Authorized Official – The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of the solicitation
- As an addendum to the cover letter:
    - Completed Representation and certifications: Offerors must have an active registration in SAM.gov (https://beta.sam.gov/), with completed representations and certifications, by the close date of the solicitation. Proposals submitted by offerors not registered in SAM.gov will not be considered. The Offeror shall provide a statement certifying that all company information listed in the SAM.gov website is complete, accurate, and current. If the offeror's current SAM.gov registration is incorrect or out of date, the Offeror shall complete Section 9.2 of the solicitation, "Offeror Representations and Certifications." In such a circumstance, one (1) originally signed copy of Section 9.2 shall be included in the offeror's proposal.

    - Organizational Conflict of Interest (OCI) statement: Offerors shall identify any possible actual, potential or apparent OCIs which may affect the offeror's ability to perform this requirement in an impartial and objective manner or that may result in an unfair competitive advantage and any plans to mitigate any OCI issues. If the OCI mitigation plan is deemed unacceptable, the offeror will not be eligible for award. If there is no potential OCI, the offeror must provide a written statement indicating this.

Volume I-Technical Proposal

The technical volume is limited to 25. A page in the technical volume that contains a table, chart, graph, etc., is subject to the page limitation, unless otherwise excluded, as follows. Cover pages, table of contents, dividers, resumes, and commitment documentation are not included in the page limit. **Volume I shall not make reference to any pricing data.**

The technical proposal is an important item in the evaluation of an Offeror's capability to perform the desired services. Therefore, Offerors proposals must present sufficient information and detail to permit the Government to make an evaluation of the technical proposal without further information being required. General statements that the Offeror can or will "comply with the requirements", that "standard procedures will be used", that "well-known techniques will be used", or paraphrases of the solicitation's Statement of Work in whole or in part, will not constitute compliance. The offeror shall clearly state any areas in which assumptions are based or clearly state areas that deviate from the requirements stated in the scope of work.

The following instructions summarize the information required to facilitate the Government's evaluation of each Offeror's technical capabilities.

Technical Factor 1-Technical Understanding and Approach

A narrative description of the Offeror's approach to performing the work described in statement of work (SOW). The narrative shall address each of the following requirements contained in the solicitation including significant difficulties, obstacles and risks in performing the requirement and explain how the perceived difficulties and obstacles will be overcome and the risks managed or mitigated.

Factor 2: Key Personnel

The offeror shall provide a narrative for all the key personnel working on this contract. The narrative shall describe the roles of the key personnel and the expected contributions of the individual identified. The offeror shall include resumes (not more than two pages) for everyone identified as key personnel along with letters of commitment

Factor 3: Relevant Past Performance

The offeror shall provide a narrative description of three (3) examples of experience on current and previous contracts over the past three (3) years which are relevant in terms of type, scope, complexity, and size. Offerors shall cite examples of experience that demonstrate the Offeror's ability to overcome difficulties encountered during performance with minimum impact to the program. Relevant experience submissions shall not exceed two pages for each experience provided. FDA may consider any and all

relevant Past Performance information received from any and all sources (e.g., all information readily available in CPARS).

In addition to the narrative described above, for each contract provide the following information:

1. Name of contracting activity (Federal Government agency, local government, commercial customer);
2. Contract number;
3. Contract type;
4. Total contract value;
5. Contract work (description of experience, degree of involvement, size of the organization, etc.);
6. Contracting Officer contact information (phone, fax, email);
7. Project Officer/Contracting Officer's Technical Representative contact information (phone, fax, email).

Volume II, Factor 4-Cost/Price (Business) Proposal

The offeror shall submit a business proposal fully supported by cost information adequate to determine the reasonableness of the proposed burdened labor rates and to evaluate whether the proposed prices are consistent with the level of effort described in the technical proposal. There is no page limitation for the business volume.

Cost or Pricing Data

The Offeror shall submit other than cost or pricing data. The offeror's proposal must include the identification of pricing data and an explanation of the estimating process. All costs/pricing shall be submitted in part in native format provide on Excel Spreadsheet (not PDF). The breakdown of costs/price shall be shown for each ordering period of the contract.

The offeror must indicate in its proposal whether it has the necessary financial capacity, working capital and other resources to perform the contract without assistance from any outside sources (if not, the offeror must indicate the amount required and the anticipated source).

EVALUATION CRITERIA

The following factors will be used to evaluate offers:

Volume I, Factor 1: Technical Understanding and Approach
Volume I, Factor 2: Key Personnel
Volume I, Factor 3: Past Performance
Volume II, Factor 4: Cost/Price Proposal

All non-price factors, when combined, are slightly significantly more important than cost or price. The non-price Factors 1 - 3 shall be in descending order of importance (i.e., Factor 1 is more importance than Factor 2, Factor 2 is more important than Factor 3). As technical merit of offeror proposals approach equivalence, price may become the most important factor in determining the awardee. Factors 1 and 2 will be evaluated adjectivally and categorized as Outstanding, Very Good, Acceptable, or Unacceptable. Past Performance Factor 3 will be evaluated as a risk assessment, and assessed as either High Risk, Low Risk or Neutral.

Volume I, Factor 1: Overall Technical Understanding/Approach

The Government will evaluate the extent to which the Contractor's proposed technical approach presents a sound, feasible, and workable approach to the requirements defined in sections 6.0 (Requirements) and 7.0 (Deliverables) of the statement of work. The Government will also evaluate whether the Contractor's proposed approach for assessing the abuse liability of botanical Kratom will meet FDA's objectives.

Additionally, the Government will evaluate the extent to which the Contractor's proposed mitigation strategies for the identified risks (IND submission, subject recruitment, cost management etc.) are logical and likely to be effective in decreasing the probability of the risk occurring or minimizing the impact of the risk.

Volume I, Factor 2: Key Personnel

The Government will evaluate (1) qualifications, expertise, and availability of proposed professional and technical personnel, as evidenced by education, experience, and the successful performance of the specific duties assigned for the contract; and (2) demonstrated experience and accomplishments in managing similar or related projects/tasks of comparable scientific complexity, as evidenced by the contractor's response to solicitation The key personnel in this contract should be project manager and/or project director, senior scientist, junior scientist, laboratory technicians, and any other personnel deemed essential to perform the work.

The Government will evaluate the extent to which the proposed key personnel possess the academic qualifications, profession certifications, managerial skills, and length and variety of experience to successfully manage the HAP study.

Volume I, Factor 3: Past Performance

The Government will evaluate the extent to which the Offeror's recent (within the last five (5) years) past successful performance is similar in scope and size (dollar amount) to the requirements set forth in this statement of work (SOW). The Government reserves the right to contact references for verification or additional information, and the right to consider other relevant past performance information. The Government may call

customers, whether or not listed on the provided list, to inquire about the offeror's past performance. The Government does not assume the duty to search for data to cure the problems it finds in the information provided by the offeror. The burden of providing thorough and/or complete past performance information remains with the offeror.

Price: The Government will evaluate the level of effort for the SOW by evaluating the number of proposed hours for each of the proposed labor categories to determine the Contractor's understanding of the SOW requirements. The total evaluated price will be the sum of all proposed labor rates multiplied by the proposed number of hours for each labor category. Discounts offered will be taken into consideration. Except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests, the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. Evaluation of options will not obligate the Government to exercise the option(s).

Volume II, Factor 4: Price Evaluation

The Government will conduct its price evaluation and price analysis using one or more of the techniques specified in FAR 15.404-1(b). The Price/Cost proposal will not be adjectively rated. The Volume II Price proposal will be compared to the Volume I Technical proposal for consistency. Offerors' fully burdened rates, inclusive of direct labor, fringe benefits, applicable indirect costs, and any profit for each labor category will be analyzed for price reasonableness. Any proposed materials costs will also be analyzed for price reasonableness. Price Proposal evaluations shall also include an analysis for unbalanced pricing as referenced in FAR 15.404-1(g). A determination of unbalanced pricing may lead to the rejection of the Offeror as permitted in FAR 15.404-1(g)(3).

LIST OF ATTACHMENTS

1. Class/Deviation 2020-05

2. Class/Deviation 2020-02

3. Class/Deviation 2018-01

4. RFP Questions Template

5. FDA Security Article