GENERAL INFORMATION

Document Type	Sources Sought Notice (FDA-SSN-132823)
Response Due Date:	May 8, 2026
Response Method	Email to: **ryan.alexander@fda.hhs.gov**
Point of Contact	Ryan Alexander Contract Specialist Office of Acquisition and Grants Services (OAGS) U.S. Food and Drug Administration Email: ryan.alexander@fda.hhs.gov
DESCRIPTION	**Purchase of Reference Standards for Bioanalytical Method Development in Menopause Hepatic Study**

This is a Food and Drug Administration (FDA) Small Business Sources Sought Notice for Commercial Supplies. This is NOT a solicitation for proposals, proposal abstracts, or quotations.

The purpose of this notice is to obtain information regarding: (1) the availability and capability of qualified small business sources; (2) whether they are small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; woman-owned small businesses; or small disadvantaged businesses; and (3) their size classification relative to the North American Industry Classification System (NAICS) code for the proposed acquisition 325412 – Pharmaceutical Preparation Manufacturing, with a small business standard size of 1,250 employees. The Product Service Code (PSC) is 6505: Drugs and Biologicals.

Responses to the information requested will assist the Government in determining the appropriate acquisition method, including whether a set-aside is possible. An organization that is not considered a small business under the applicable NAICS code is still encouraged to submit a Capabilities Statement.

QUESTIONS WILL NOT BE ENTERTAINED AS A RESULT OF THIS NOTICE

Background

The Division of Applied Regulatory Science (DARS) OCP/OTS/CDER is conducting a research project to examine the effect of menopausal female sex hormones on in vitro drug metabolism and transport. As part of this process, DARS needs to procure reference standards and internal standards to perform bioanalytical method development and sample analysis to determine the quantification of CYP enzyme substrates/metabolites and transporter substrates in hepatocyte experiments.

Objectives

The objective of the contract is to obtain critical reagents such as procure reference standards and internal standards to perform bioanalytical method development and sample analysis to determine the quantification of CYP enzyme substrates/metabolites and transporter substrates in hepatocyte experiments.

Scope

FDA is seeking to purchase the supplies necessary for the execution of a study in DARS laboratories in collaboration with the Office of Women's Health.

Deliverables / Tasks

- The Contractor shall provide the following deliverables:

Independent Government Cost Estimate					
Purchase of Reference Standards for Bioanalytical Method Development in Menopause Hepatic Study					
	Compound	**Weight (mg)**	**Price**	**Quantity**	**Total**
	Phenacetin	50.00	$0.00	4	$0.00
	Acetaminophen	100.00	$0.00	4	$0.00
	Acetaminophen-d4	5.00	$0.00	4	$0.00
	Bupropion HCl (5mg)	5.00	$0.00	4	$0.00
	Hydroxybupropion	5.00	$0.00	4	$0.00
	Hydroxybupropion-d6	1.00	$0.00	4	$0.00
	S-Mephenytoin	10.00	$0.00	4	$0.00
	4-hydroxymephytoin	5.00	$0.00	4	$0.00
	4'-hydroxymephytoin-d3	2.50	$0.00	4	$0.00
	S- (-)-Warfarin	5.00	$0.00	4	$0.00
	7-OH-warfarin	5.00	$0.00	4	$0.00
	7-Hydroxy Warfarin-d5	1.00	$0.00	4	$0.00
	Bufuralol HCl	1.00	$0.00	10	$0.00
	1-OH-	1.00	$0.00	4	$0.00

	Bufuralol HCl				
	1-Hydroxy Bufuralol-d9	0.50	$0.00	4	$0.00
	Midazolam	100.00	$0.00	4	$0.00
	1-OH-Midazolam	5.00	$0.00	4	$0.00
	1-Hydroxy Midazolam-d5	1.00	$0.00	4	$0.00
	Metformin	10.00	$0.00	8	$0.00
	Metformin-d6 HCl	1.00	$0.00	4	$0.00
	Rosuvastatin Calcium Salt	10.00	$0.00	8	$0.00
	Rosuvastatin-d6 Sodium Salt	1.00	$0.00	4	$0.00
	Telmisartan	10.00	$0.00	8	$0.00
	Telmisartan-d3	1.00	$0.00	4	$0.00
	Meloxicam	25.00	$0.00	8	$0.00
	Meloxicam-d3	1.00	$0.00	4	$0.00
	17-beta-Estradiol	250.00	$0.00	4	$0.00
	Progesterone	250.00	$0.00	4	$0.00
	Estrone	100.00	$0.00	4	$0.00
	Estrone D2 (16,16-D2)	10.00	$0.00	4	$0.00
	Shipping & Handling	N/A	$0.00	2	$0.00
TOTAL		$0.00			
*Quantity: number of vials					

Chemical Quality Requirements:

- All compounds must be reference standard grade materials
- Certificates of analysis must be provided for each compound
- Proper storage conditions must be maintained during shipping and storage
- Expiration dates must allow for completion of the study
- All chemicals must be packaged in appropriate containers with proper labeling
- Temperature-controlled shipping required for temperature-sensitive compounds
- Chain of custody documentation must accompany all shipments

Documentation Requirements:

- Individual certificates of analysis for each compound showing purity, identity confirmation, and stability data
- Material Safety Data Sheets (MSDS) for all compounds
- Chain of custody forms
- Storage and handling recommendations for each compound

Task 1 – Chemical Shipment

- Shipment of all items described in section 4.0

Task 1, Notification of Compound Unavailability

- If compounds are out of stock or otherwise unavailable the vendor shall notify the Project Officer within 14 days of the award date.

Delivery

All deliverables required under this contract shall be packaged, marked, and shipped in accordance with Government specifications:

- All chemicals must be packaged according to applicable DOT regulations
- Dry ice or other appropriate temperature control during shipping
- Proper hazardous material labeling and documentation
- The Contractor shall guarantee that all required materials shall be delivered in immediate new, usable, and acceptable condition to the address as shown below.

  US Food and Drug Administration
  10903 New Hampshire Ave, WO 64 Rm 2064
  Silver Spring MD 20993
  Attn: TBD

  Freight should be delivered to WO Bldg 62 Loading Dock, and then to WO64-2064.

  Vendor shall contact the Project Officer: TBD
  by phone or email to schedule delivery within 14 days of the award date.

  Deliveries must be coordinated with the Project Officer prior to shipment. No deliveries will be accepted without prior authorization from the Project Officer.

Deliverables

This table lists the deliverables for the Information & Information Technology Security & Privacy Standards. Note that these are not the only deliverables for this contract.

Section	Title	Deliverable Description	Due Date	Applicable
1.1	Contractor Employee Non-Disclosure Agreement (NDA)	NDA	After contract award, with each onboarding request	☐
1.1	Privacy Threshold Analysis (PTA)/ Privacy Impact Assessment (PIA)	Assist in the completion of a PTA/PIA	Per timeline as specified by the FDA Privacy POCs after contract award	☐
1.2	Training Records	Copy of training records for all mandatory training	In conjunction with contract award and annually thereafter or upon request	☐
1.3	Rules of Behavior	Signed ROB for all employees	Initiation of contract and at least annually thereafter	☐
1.4	Incident Response	Incident Report (as incidents or breaches occur)	As soon as possible and without unreasonable delay and no later than 1 hour after discovery to the FDA Cybersecurity and Infrastructure Operations Coordination Center (CIOCC) 855-533-2762/301-796-6622/ ciocc@fda.hhs.gov.	☐
1.4	Incident Response	Incident and Breach Response Plan	Upon request from government	☐
1.5	Background Investigation	Onboarding documentation when beginning contract	Prior to performing any work on behalf of HHS/FDA	☐
1.5	Personnel Security Responsibilities	List of Personnel with defined roles and responsibilities	Within a period directed by the COR that is before an employee begins	☐

			working on this contract.	
1.7	Roster	Roster	Within time a period directed by the COR of the effective date of this contract.	☐
1.8	Personnel Security Responsibilities	Off-boarding documentation, equipment and badge when leaving contract	The last day that work is being performed after the Government's final acceptance of the work under this contract, or in the event of a termination of the contract.	☐
1.8	Certification of Sanitization of Government and Government Activity-Related Files, Information, and Devices.	Form or deliverables required by FDA.	Prior to contract expiration or as directed by the COR.	☐
1.8	Contract Initiation and Expiration	If the procurement involves a system or cloud service, additional documentation will be required, such as Disposition/Decommission Plan	Prior to contract expiration, or as directed by COR.	☐
3	Assessment and Authorization (A&A)	A&A Package • SSP • POA&M • Authorization Letter • CP and CPT Report • E-Auth (if applicable) • PTA/PIA (if applicable) • Interconnection/Data Use Agreements (if applicable) • Authorization Letter • Configuration		☐

		Management Plan (if applicable) • Configuration Baseline • Other FDA-specific documents		
4.2	Protection of Information in a Cloud Environment	Contract expiration	Due within 30 days after contract award.	☐
4.1 4.3	A&A Process for Cloud Services	Cloud A&A Package • SSP • SAR • POA&M • CMP • CP and CPT Report • E-Auth (if applicable) • PTA/PIA (if applicable) • Penetration Test Results Interconnection/Data Use/Agreements (if applicable) • Service Level Agreement Authorization Letter		☐
4.4	Reporting and Continuous Monitoring	• POA&M updates • Revised security documentation/Agreements	Monthly/as requested by FDA	☐
	Security Alerts, Advisories, and Directives	List of personnel with designated roles and responsibilities	FDA-Specified	☐
4.6	Incident Reporting	• Incident reports (as needed) • Incident Response Plan	FDA-Specified	☐
6	Other IT Procurements (Non-	Computer software, including the source code.	Prior to performing any work on behalf of HHS/FDA	☐

	Commercial and Open-Source Computer Software Procurements)			

Travel
N/A

Special Material Requirements
N/A

Place of Performance
The Contractor will perform all work at its own facilities.

Period of Performance

The anticipated period of performance is six (6) months from date of award**.**

Capabilities and Technical Experience

Provide a capability statement describing how your company would be able to meet the requirements.

Business Status

Please provide your business size status (e.g., small business, 8(a), HUBZone, etc.) and SAM.gov Unique Entity Identifier (UEI) number.

Disclaimer and Important Notes

This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work.

Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published in SAM.gov. However, responses to this notice will not be considered adequate responses to a solicitation.

Responses to the sources sought shall be no longer than 10 pages.