

NOTICE TO THE PUBLIC

Provide 242 peptides Center for Biologics Evaluation and Research Gene Transfer Immunogenicity Branch, Food and Drug Administration, (FDA-1257348)

This is a combined synopsis/solicitation for commercial items prepared in accordance with the format in FAR 12.6. This announcement constitutes the only solicitation, and a written solicitation will not be issued.

This requirement is “Subject to the Availability of Funds” The Following FAR Clause applies: AVAILABILITY OF FUNDS (52.232-18) (APR 1984)

This synopsis, NAICS code 325414, identified as REQ#1257348 is to notify contractors that the government intends to issue a Purchase Order in accordance with FAR Part 13.106 for the following specifications, under the simplified acquisition procedures.

Background

Food and Drug Administration, (FDA) Center for Biologics Evaluation and Research Gene Transfer Immunogenicity Branch requires a peptide library spanning the entire sequence of AAV1 VP1. These peptides will be used to identify the T cell epitopes in AAV1 capsid protein and develop new methods to detect and mitigate the immunogenicity of AAV vectors used in gene therapy vectors. This has critical relevance for the review of Gene Therapy vectors and products involved in emerging gene therapy strategies.

Purpose/Objective

We analyzed the sequence of AAV1 capsid protein and designed a list of 242 overlapping peptides, spanning the entire amino acid sequence of AAV1 VP1 capsid protein. The list is attached as appendix 1. Each of the peptides in the library will be used to stimulate T cells and map the immune response against peptide fragments derived from the capsid protein. Cells from various donors will be expanded with the peptide library. Each peptide-stimulated sample will be analyzed and studies for a cytokine immune response to each of the peptides in the library.

Work Requirements

Technical Requirements

- 242 peptides, according to the sequences in appendix 1 below:



Copy of Appendix
1_AAV1 peptide librar

- 15 mer
- At least 4mg each, aliquoted in 4 x 1 mg vials.
- Peptides will be sent in 96 format vials.
- Purity >95%
- QC Report: COA, RP-HPLC and MS for each peptide (digital or paper are both acceptable)
- Preference for endotoxin testing. Not a requirement.
- Ship all peptides in a single delivery.

Deliverables

Contractor shall deliver 242 peptides in 96 format vials and QC reports in a USB drive or paper
Due by: occur 50-100 days from date of award at a time determined by the requesting lab.

Delivery Location

Note: Shipping by FedEx or UPS

Ronit Mazor or Shiang-Ling Chu

FDA/CBER

Bldg. 52 Rm 3248

10903 New Hampshire Ave

Silver Spring, MD 20993.

Delivery will be accepted during regular business hours (Monday-Friday) during the times of 8:00 AM – 4:00 PM local Time.

Period of Performance

One Year (1) from date of Award (includes a 12-month Warranty Period)

Inspection and Acceptance

The COR and/or COR designee will perform inspection and acceptance of equipment.

A final inspection and acceptance of all deliverables will be performed by the COR and/or COR designee to ensure the products provided meet the requirements of the Statement of Work (SOW).

Inspection and acceptance will occur at the place of performance and take place within five (5) business days of task being completed. The Government will provide written notification of acceptance or rejection within five (5) business days. Inspection will include review of the deliverables to ensure adequacy.

The Government will accept goods, reports, and services only if they conform to all terms and conditions of the SOW, and satisfy the performance standards developed under this SOW.

The Government will reject non-conforming products and services. The Contractor shall correct any deficiencies within fifteen (15) business days of when the Government issues the rejection notice. If the Contractor cannot correct the deficiencies within this period, the Contractor shall immediately notify the COR of the reason for the delay and provide a proposed corrective action plan within five business days. **Note: Upon arrival, the shipping container(s) will be inspected for damage. If significant damage is observed, such as a hole going through the container and packing to reach the enclosure itself, it will be rejected.**

Contracting Officer Authority

The Contracting Officer (CO) is the sole person authorized to make or approve any changes in any of the requirements of this order and notwithstanding any provisions contained elsewhere in the order, the said authority remains solely with the CO. In the event the Contractor makes any changes at the direction of any person other than the CO, the change shall be considered to have been made without authority and no adjustment will be made in the delivery order terms and conditions, including price. The CO shall be the only individual authorized to accept nonconforming work, waive any requirement of the order, and modify any term or condition of the order. The CO is the only individual who can legally obligate Government funds.

The Contracting Officer's Representative (COR) or Project Officer is not authorized to make any commitments or otherwise obligate the Government or authorize any changes which affect the order price, terms, or conditions. The COR/Project Officer is responsible for the technical aspects of the project and serves as technical liaison with the contractor and is responsible for the final inspection and acceptance, and such other responsibilities as may be specified in the order.

Contract Type

Firm-Fixed-Price (FFP). All deliverables shall be clearly identified, complete with clear descriptions; due dates, and at a predetermined, agreed-upon price.

Government Contacts

Contracting Officer: (CO):

Office of Acquisitions Grants and Services

Mary Rose A. Nicol, CO

Phone: 240-402-7606

Email: Maryrose.nicol@fda.hhs.gov

Contracting Officer Representative, (COR)

TBD

Government Holidays

Unless otherwise specified, the Contractor shall perform work Monday through Friday (excluding Federal Holidays) between the hours of 8:00 a.m. and 4:30 p.m. EST. Supplies or services scheduled for delivery on a Federal holiday shall be made the next business day. Workplace is not available on the Government Holidays stated below, or as prescribed by an Executive Order (EO) due to inclement weather.

- New Year's Day
- Martin Luther King Day
- President's Day
- Memorial Day
- Juneteenth National Independence Day
- Independence Day
- Labor Day

- Columbus Day
- Veteran 's Day
- Thanksgiving Day
- Christmas Day

BASIS OF AWARD

The Government will award a contract resulting from this solicitation to the responsible quoter as a fixed-price contract on the lowest price technically acceptable (LPTA) evaluation method.

Award will be made on the basis of the lowest evaluated price meeting or exceeding the non-cost factor (technical conformance to the requirements of the solicitation). The Quoter's initial quotation shall contain the Quoter's best terms from a price standpoint. Failure to demonstrate meeting any of the requirements will result in a rating of technically unacceptable and will not be considered for award.

In order to facilitate the award process, ALL quotes shall include a statement regarding the terms and conditions herein. Additionally, all quotes shall include price (s); FOB point; a poc (name and telephone number); a statement from the offeror verifying that they are Registered in SAM.gov under NAICS code; 334516_delivery date (delivery date is of the utmost importance); business size; and payment terms. Delivery shall be to FDA.

FDA intends to make an award soon after the response date of this notice and all quotes must be submitted via email to Maryrose.nicol@fdahhs.gov and be received by 5:00 PM (1700) on , August 24, 2022 to the attention of Mary Rose A. Nicol, maryrose.nicol@fda.hhs.gov. Offerors shall ensure the RFQ number is visible in the header of the email.

ALL QUESTIONS REGARDING THIS SYNOPSIS/SOLICIATION MUST BE SUBMITTED IN WRITING NO LATER THAN 5:00 PM (1700) EST August 22, 2022. FAX QUOTES SHALL NOT BE ACCEPTED.

