



Notice of Intent to Sole Source

Notice Number: 75F40123Q00341
Requirement Title: PAK BioSolutions Parts/Components
Posting Date: 08/07/2023
Closing (Response) Date: 08/14/2023 at 10:00 a.m. Eastern Time (ET)

The U.S. Food & Drug Administration (FDA) intends to issue a sole-source commercial product purchase order to PAK BIOSOLUTIONS, INC. located at 8607 Westwood Center DR, STE 560 Vienna, Virginia 22182-7506.

An award is anticipated to be made using Simplified Acquisition Procedures and under the authority of Federal Acquisition Regulation (FAR) Part 13.106-1(b)(1)(i) wherein the circumstances of the proposed contract action deem only one source reasonably available.

The FDA's Center for Drug Evaluation and Research (CDER), Office of Biotechnology Products (OBP) currently owns and operates a PAK BioSolutions Pilot PAK200 system for integrated continuous purification of biopharmaceuticals. The current workload of this instrument requires regular replacement of operational parts, components, and peripherals compatible with the Pilot PAK200 system that are provided only by the Original Equipment Manufacturer, PAK BioSolutions.

This notice is not a request for competitive quotations. However, any party that believes it can meet this requirement as stated herein may submit a written capability statement that clearly supports and demonstrates their ability to perform the requirement.

Capability statements must be received by the response date and time of this notice. Submissions will be reviewed to determine if they can meet the requirement. A determination by the Government to compete this proposed award based upon responses to this notice is solely within the discretion of the Government.

It is anticipated that an award will be issued to PAK BIOSOLUTIONS, INC. within approximately five (5) days after the response date of this notice unless the Government determines that any other organization has the capability to meet this requirement.

Response Date: 08/14/2023 at 10:00 a.m. ET. Please email responses to Contract Specialist Benjamin Dorgan at benjamin.dorgan@fda.hhs.gov. No phone calls will be accepted.