

NAVAL MEDICAL LOGISTICS COMMAND  
 JUSTIFICATION AND APPROVAL  
 FOR USE OF OTHER THAN FULL AND OPEN COMPETITION

1. Contracting Activity. Naval Medical Logistics Command (NMLC), Fort Detrick, Maryland on behalf of the Department of Defense (DOD) Drug Demand Reduction Program (DDRP) Office.

2. Description of the Action Being Approved. Award of a contract on a sole source basis for immunoassay reagent kits for the simultaneous detection of designer methamphetamines (MDMA, MDEA and MDA) in urine from Microgenics Corporation. Authority to act under this class justification expires on 31 May, 2013.

3. Description of Supplies/Services. The DOD DDRP requires an immunoassay reagent kit for the simultaneous detection of designer methamphetamines (MDMA, MDEA and MDA) in urine. The proposed bridge contract will be for a period of three months (base period 01 June 2013 – 31 August 2013) with a requirement of 200 estimated kits per month. The period of performance will also include two, one-month option periods (option period 01: 01-30 September 2013, option period 02: 01-31 October 2013) with a requirement of 200 estimated kits per month.

This is a requirements contract; therefore, funding will be provided on each individual delivery order. The estimated dollar value of the proposed contract follows:

Base Period	Option Period 1	Option Period 2	Total
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

4. Statutory Authority Permitting Other Than Full and Open Competition. 10 U.S.C. 2304(c)(1), One source or limited sources and FAR 6.302-1 only one responsible source and no other supplies or services will satisfy agency requirements.

5. Rationale Justifying Use of Cited Statutory Authority. The current contract, [REDACTED] for designer methamphetamines reagent kits, expires 31 May 2013. No award was made for the follow-on contract, solicitation [REDACTED], which was set to replace the current bridge contract, [REDACTED]. Two offerors responded to the solicitation.

- The evaluation factors for solicitation [REDACTED] were:
- Evaluation Factor A – FDA and ISO Certification
  - Evaluation Factor B – Reagent Preparation and Calibration Information
  - Evaluation Factor C – Performance Test – Minimum Requirements
  - Evaluation Factor D – Performance Testing – Enhancing Factors
  - Evaluation Factor E – Past Performance
  - Evaluation Factor F – Price

The relative importance of each factor was as follows: Evaluation Factor A – FDA and ISO Certification and Evaluation Factor B – Reagent Preparation and Calibration Information were evaluated individually on a pass/fail basis. If an offeror's technical proposal was judged to have failed under Evaluation Factors A or B, either initially or following discussions if they were conducted, the firm's offer received no further consideration for award unless there were no other technically compliant proposals. If an offeror's technical proposal was judged to have passed both Evaluation Factors A and B, then the offeror was subsequently notified of Evaluation Factor C, the performance test of their reagent to determine compliance. If an offeror's technical proposal was judged to have failed under Evaluation Factor C, the firm's offer received no further consideration for award unless there were no other technically compliant proposals. If an offeror as judged to have passed under all Evaluation Factors A, B, and C minimum requirements, then the firm's offer was further evaluated on a trade off basis taking into consideration Evaluation Factors D-F. In doing so, Factor D – Performance Test – Enhancing Factors, was more important than Factor E – Past Performance. The combination of Evaluation Factors D and E was significantly more important than F – Price.

Both offerors passed Evaluation Factor A – FDA and ISO Certification and Evaluation Factor B – Reagent Preparation and Calibration Information; however, both offerors failed Evaluation Factor C – Performance Testing – Minimum Requirements. Evaluation Factor C for solicitation N62645-12-R-0049 was completed on 18 March 2013. On 20 March 2013 the Technical Evaluation Team from the DOD DDRP notified NMLC that both offerors failed Evaluation Factor C, and due to the deficiencies, it was doubtful that proposals could be make acceptable through discussions with the offerors. As a result, the contract specialist reviewed the Technical Evaluation Board's evaluation with the contracting officer and legal counsel. Based on the technical evaluation, the contract specialist, contracting officer, and legal counsel determined the following: the offerors would be notified that their proposal had failed Evaluation Factor C, and because no offerors were deemed acceptable, no award would be made. As a result on 28 March 2013, both offerors were notified they had been excluded from the competitive range and an amendment was issued to cancel the solicitation.

The re-solicitation effort for Designer methamphetamines reagent kits is currently in the early stages of the procurement process. The DoD DDRP is in the process of modifying the evaluation criteria to be used in the re-solicitation of Designer methamphetamines. The modified evaluation criteria will ensure potential offerors can satisfy the minimum requirements while considering the needs of the DoD DDRP. It is unlikely that the procurement process can be completed in time to make a sound contract award with sufficient start up time to provide the Designer methamphetamines reagent kits prior to the 31 May 2013 expiration of the current contract, [REDACTED].

The extension of the contract with Microgenics Corporation is necessary in order to provide continuity of service for the DOD Drug Demand Reduction Program because only one source, Microgenics Corporation, has the capability, the resources, the contacts, and the expertise to immediately continue providing these urgent and critical designer methamphetamines reagent kits, thereby avoiding a costly and potentially break in critical drug testing services. These services protect the interest and concerns of military and civilian members and our nation by providing identification and preventative action of drug abuse and potential drug overdose. To re-compete at this time would result in a lapse in production that would have a direct and

negative impact on the testing and prevention of drug abuse of our military and civilian members as well as impact the integrity of the DOD Drug Demand Reduction Program.

6. Description of Efforts Made to Solicit Offers from as Many Offerors as Practicable. This requirement will be synopsisized on the Navy Electronic Business Opportunities (NECO) and Federal Business Opportunities (FEDBIZOPPS), pursuant to Part 5 of the Federal Acquisition indicating the Government's intent to award a three month bridge contract with two, one month option periods on a sole source basis to Microgenics Corporation base period 01 June 2013 – 31 August 2013, option period 01: 01 -30 September 2013, option period 02: 01- 31 October 2013. Currently no other sources will be solicited. If another company submits a written interest in this requirement as a result of the announcement, the company's information will be evaluated before the contract is signed with Microgenics Corporation.

7. Determination of Fair and Reasonable Cost. The Contracting Officer has determined the anticipated cost to the Government of the supplies/services covered by this J&A will be fair and reasonable.

8. Actions to Remove Barriers to Future Competition. The supplies in the interim contract are concluded when the designer methamphetamines reagent kits re-solicitation is awarded. The re-solicitation is a competitive follow-on procurement.

9. CONTRACTING POINT OF CONTACT. The contracting point of contact at the Naval Medical Logistics Command, Fort Detrick, Frederick, MD, regarding the contents of the sole source justification is [REDACTED], who may be reached at [REDACTED].

**CERTIFICATIONS AND APPROVAL**

**TECHNICAL/REQUIREMENTS CERTIFICATION**

I certify that the facts and representations under my cognizance which are included in this Justification and its supporting acquisition planning documents, except as noted herein, are complete and accurate to the best of my knowledge and belief.

Technical/Requirements Cognizance

\_\_\_\_\_  
Signature                      Name (Printed)                      Phone No.                      Date

**LEGAL SUFFICIENCY REVIEW**

I have determined this Justification is legally sufficient.

\_\_\_\_\_  
Signature                      Name (Printed)                      Phone No.                      Date

**CONTRACTING OFFICER CERTIFICATION**

I certify that this Justification is accurate and complete to the best of my knowledge and belief. To the extent that the J&A/LSJ value is between \$150K and \$650K, the Contracting Officer's signature below also represents approval of the J&A/LSJ.

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Signature                      Name (Printed)                      Phone No.                      Date