

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: March 2, 2017

Re: Sole Source Certification Number **SS5084** for **INOtherapy® Services**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5084** for **INOtherapy® Services**, please be advised that UMMC intends to award to **INO Therapeutics LLC dba Mallinckrodt** as the sole source provider of the **nitric oxide-based inhalation therapy, INOtherapy®**.

UMMC issues this notice in accordance with Mississippi state law, policy, and procedures for sole source procurements.

Sole Source Criteria

1. Where the compatibility of equipment, accessories, or replacement parts is the paramount consideration (and manufacturer is the sole supplier).
2. Where a sole supplier's item is needed for trial use or testing.
3. Where a sole supplier's item is to be required when no other item will service the needs of UMMC.

Schedule

Task	Date
First Advertisement Date	March 2, 2017
Second Advertisement Date	March 9, 2017
Response Deadline from Objectors	March 16, 2017, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before June 16, 2017

Project Details

1. Describe the commodity that the agency is seeking to procure:

The University of Mississippi Medical Center is requesting the purchase of the INOtherapy® therapeutic system, which includes the pharmaceutical INOmax® from INO Therapeutics LLC dba Mallinckrodt. This product and all accessory devices are needed for delivery of inhaled nitric oxide. Inhaled nitric oxide is used extensively throughout critical care, perioperative, and emergency services within UMMC. Nitric oxide is delivered to the patient via mechanical ventilation after dilution with an oxygen/air mixture using an approved (CE-marked) nitric oxide delivery system. Inhaled nitric oxide causes vasodilation in the pulmonary vasculature.

2. Explain why the commodity is the only one (1) that can meet the needs of the agency:

INOtherapy® is an all-inclusive offering of drug product (INOMAX®), services and technologies. INOtherapy® includes FDA-approved pharmaceutical grade INOMAX® (nitric oxide) for inhalation, INOcal® calibration gases, use of Ikaria's proprietary drug-delivery system, distribution, emergency delivery, technical and clinical assistance, quality maintenance, in-service training and 24-hour technical service.

3. Explain why the source is the only person or entity that can provide the required commodity:

INO Therapeutics LLC dba Mallinckrodt is the sole manufacturer and distributor of INOtherapy®. INOtherapy® is not available from any other distributor. See supporting letter from VENDOR, Attachment A.

4. Explain why the amount to be expended for the commodity is reasonable:

The estimated amount to be expended for the purchase of INOtherapy® is \$2,742,996.00/year; 12 monthly installments of \$228,583.00. This amount is within the expected price range for these products.

5. Describe the efforts that the agency went through to obtain the best possible price for the commodity:

Through market intelligence, UMMC was able to negotiate best pricing for these products. All applicable discounts were explored and applied.

Submission Instructions and Format of Response from Objecting Parties

Interested parties who have reason to believe that the **INOtherapy® Services** (hereafter, “Products”) should not be certified as a sole source should provide information in the Vendor Form for the State to use in determining whether or not to proceed with awarding the sole source to **INO Therapeutics LLC dba Mallinckrodt**.

The Vendor Form may be found at

<http://www.dfa.state.ms.us/Purchasing/documents/ObjectiontoSoleSourceDetermination.pdf>.

Objections must include the certification in Attachment B.

Comments will be accepted at any time prior to March 16, 2017, at 3:00 p.m. (Central Time) to solesource@umc.edu. Responses may be delivered via email to solesource@umc.edu. UMMC WILL NOT BE RESPONSIBLE FOR DELAYS IN THE DELIVERY OF RESPONSES. It is solely the responsibility of the Interested Parties that responses reach UMMC on time. Responses received after the deadline and responses that lack all required information will be rejected. UMMC reserves the right to inspect Interested Party’s commodity for comparison purposes.

If you have any questions concerning the information above or if we can be of further assistance, please contact solesource@umc.edu.

Attachment A: Vendor Correspondence

Attachment B: Objection Certification

Attachment A



February 15, 2017

Re: INO Therapeutics LLC d/b/a Mallinckrodt - Sole Source Statement

Dear Valued Customer:

INO Therapeutics LLC d/b/a Mallinckrodt is the sole source provider of nitric oxide-based inhalation therapy, INOtherapy®, in the United States. INOtherapy includes our pharmaceutical, INOmax® (nitric oxide) for inhalation (NDC numbers 64693-002-01 and 64693-002-02).

Please feel free to call if you have questions or need additional information.

Best regards,

A handwritten signature in black ink that reads "Lori Donohue".

Lori Donohue
Contracts Manager
(908) 238-6668
critcare-contracts@mallinckrodt.com

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5084
Accepted until March 16, 2017, at 3:00 p.m.**

I certify that the information contained in this objection is true and accurate to the best of my knowledge. I understand that UMMC will investigate all statements made in this objection and that any false or misleading information provided may result in adverse action.

Objector Name
Objector's title

Date