

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: January 12, 2017

Re: Sole Source Certification Number **SS5072** for **Therakos CELLEX Photopheresis System and associated commodities**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5072** for **Therakos CELLEX Photopheresis System and associated commodities**, please be advised that UMMC intends to award the purchase of the **Therakos CELLEX Photopheresis System and associated commodities** to **Therakos, Inc., a division of Mallinckrodt Pharmaceuticals** as the sole source provider of the **Therakos CELLEX Photopheresis System and associated commodities**.

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	January 12, 2017

Second Advertisement Date	January 19, 2017
Response Deadline from Objectors	January 27, 2017, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before February 17, 2017

Project Details

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

The University of Mississippi Medical Center (UMMC) seeks to purchase the Therakos CELLEX Photopheresis System and associated commodities. Photopheresis, also known as Extracorporeal Photopheresis (ECP), is an immune modulation therapy that was approved by the FDA for the palliative treatment of the skin manifestations of Cutaneous T-Cell Leukemia (CTCL). ECP is also known as photo-immune therapy or immune cell therapy, and works by using either the integrated Therakos photopheresis systems to collect a small amount of whole blood from a patient connected to the system. The system then separates the white blood cells, treats them with an ex-vivo methoxsalen (8-MOP) sterile solution, a photo-actable substance; activates the methoxsalen by UVA light; and reinfuses the white cells back into the patient. The treated white cells will start to undergo normal programmed cell death (apoptosis), which triggers a cascade of immunologic events. Less than 10% of all white cells are treated, yet some patients achieve a complete improvement in symptoms.

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

The Therakos photopheresis systems are the only integrated, FDA approved photopheresis devices. ECP helps to restore the body's natural ability to maintain a balanced immune system by controlling the activity of overactive immune cells. Healthy immune systems maintain a balance between the effector cells that fight infection and the regulatory cells that prevent immune-mediated diseases like CTCL. Other therapies for restoring a balanced immune system have traditionally targeted the effector cells by suppressing their function, thus suppressing the immune system. However, ECP is believed to boost the number of the regulatory cells (T-regs) of the immune system, providing a novel approach that may have significant activity in the treatment of disease, including skin manifestations, without inducing generalized immunosuppression.

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

Therakos, Inc. is the sole manufacturer and distributor of the Therakos CELLEX Photopheresis System and associated commodities. See supporting letter from **Therakos, Inc., a division of Mallinckrodt Pharmaceuticals**, Attachment A.

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

The estimated amount to be expended is for the purchase of the **Therakos CELLEX Photopheresis System and associated commodities** is \$3M for the term of the contract. 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 **Therakos CELLEX Photopheresis System and associated commodities** (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 **Therakos, Inc., a division of Mallinckrodt Pharmaceuticals**. 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 Friday, January 27, 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



December 19, 2016

University of Mississippi
2500 North State Street
Jackson, MS 39216

Dear Valued Customer:

You have requested a letter verifying that Therakos is the sole source provider of Photopheresis equipment in the US. Therakos is also the sole source provider for all Photopheresis System Procedural Kits and UVADEX (methoxsalen) Sterile Solution.

The THERAKOS® CELLEX® Photopheresis System and THERAKOS® UVAR XTS® Photopheresis System are the only FDA approved devices for extracorporeal Photopheresis.

The THERAKOS® UVAR XTS® Photopheresis System and THERAKOS® CELLEX® Photopheresis Systems are indicated the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) in persons who have not been responsive to other forms of treatment.

If you would like any further information, please feel free to contact me.

Thank You,

A handwritten signature in black ink, appearing to read "Diane Nazimek", written over a circular stamp.

Diane Nazimek
Senior Analyst, Contracting
908-238-6387
diane.nazimek@mallinckrodt.com

Attachment B

SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5072
Accepted until January 27, 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