## LIMITED SOURCE JUSTIFICATION

- 1. Defense Logistics Agency (DLA) Troop Support, Medical Supply Chain, Capital Equipment Division, is the contracting activity.
- 2. This justification is for the acquisition of brand name products or features essential to the Department of Health and Human Services (HHS) requirements under Marketing Assessment's Electronic Catalog (ECAT) contract number SPM2D1-14-D-8200. This contract expires September 30, 2018.
- 3. HHS has requirements for the following item:

National Stock Number (NSN): 6510-01-522-2173 Item Description:

Silver Impregnated Dressing (SID), 4" x 66", Argentum Medical, LLC Silverlon ®.

Argentum Medical and Marketing Assessment Part Number (P/N) BWD-466

Quantity: 25,200 each

4. The authority waiving the competition requirements is FAR 8.405-6(b)(1), only one source is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.

HHS has a requirement to procure SIDs to update the contents of the Burn-Blast Kits held in the Strategic National Stockpile (SNS) within the Centers for Disease Control and Prevention (CDC). The Burn-Blast Kit products, including SIDs, are intended to provide immediate field care for thermal burn injuries/wound trauma for thousands of civilians in resource constrained environments during mass casualty incidents.

The following minimum requirements were established by HHS for the SID:

- a. The SID shall have a Food & Drug Administration (FDA) premarket clearance
- b. The SID shall have a minimum shelf life of five (5) years
- c. The SID shall have a minimal need for ancillary supplies when applying the dressingnothing more than standard medical gauze/tape for secondary dressings
- d. The SID shall be able to meet CDC Burn-Blast Kit Configuration and Footprint Requirements for the Strategic National Stockpile

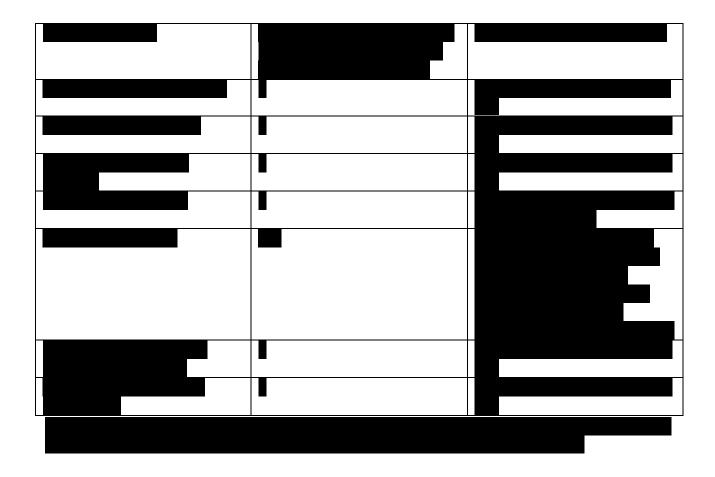
The CDC requires that SIDs be packaged in an optimal way to maximize the amount of product available in the kit while minimizing logistical footprint to meet this requirement. The SID shall be supplied in a rolled product configuration, not as individual sheets. This will allow for optimally placing SIDs directly into the Burn-Blast Kits. The roll-configuration is required to meet the operational need for rapid field care for burn injuries during a mass casualty. Since HHS will be storing these dressings in the Burn Blast Kits, a very long product shelf life meeting the minimum

shelf life requirements identified above is absolutely essential. The intended use of SIDs is to prevent from infection and promote healing while the intended use of a regular dressing (e.g. gauze dressing) is only to prevent infection by keeping the burnt/wound area dry. Regular dressings/bandages do not promote the healing of the burn victim. In addition, regular dressing is required to be applied/ changed more frequently. The SID can be used for several days.

| DLA Troop Support has already determined the prices of supplies under  | the FCAT            |
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| multiple award program fair and reasonable.  |                     |
|  | A determination has |
| been made by the contracting officer that this order represents the best va<br>Government and results in the lowest overall cost alternative (considerin |                     |
| features, and administrative cost) consistent with FAR 8.404(d).   | ig price, special   |

6. (a) Extensive Market Research has been conducted by the Office of Biomedical Advanced Research and Development Authority (BARDA) within the U.S. Dept. of Health and Human Services. This market research has been ongoing since 2012. This included soliciting feedback from civilian and military burn surgeons, hosting and attending conferences with professional societies such as the American Burn Association, and holding discussions and forums with key product manufacturers.

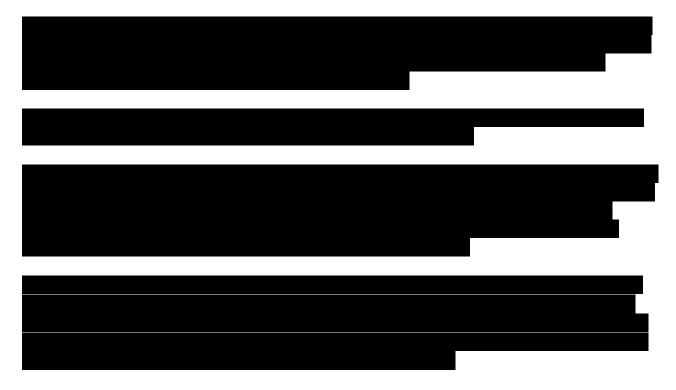




## (b) Updated Market research as of November of 2017:

Since 2015, BARDA has continued its market research for SIDs through extensive discussions with leading U.S. burn surgeons, evaluating product vendors at national and international burn injury conferences, conducting internet and scientific publication searches, inviting potential vendors to BARDA Industry Day conferences and through BARDA's TechWatch program, and exchanging information with DoD research and development programs, mainly the US Army Institute for Surgical Research (USAISR).

| Additional market research was also performed in the ECAT system by DLA in November 2017. |
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- 7. There are no additional facts supporting this justification.
- 8. Any ECAT vendor not currently offering the required product will have the opportunity to add the product, enhancing competition. Furthermore, ECAT vendors have the opportunity to add products that fall within the scope of the ECAT contract at any time. DLA Troop Support will attempt to locate other acceptable sources for future requirements as they arise; however any new item would be required to meet HHS's requirements.
- 9. As the Contracting Officer, I hereby certify that the information contained in this Limited Source Justification is accurate and complete to the best of my knowledge and belief.



I hereby certify that the requirements which form the basis of this justification are accurate, that these supplies meet the Government's minimum needs and that this justification is accurate and complete to the best of my knowledge and belief.



I have reviewed the justification and recommend approval.



I have reviewed the justification and recommend approval.



I have reviewed the justification for legal sufficiency.



I have reviewed and hereby approve this justification.

