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Comptroller General
of the United States

United States Government Accountability Office
Washington, DC 20548

Decision

Matter of: Veterans Healthcare Supply Solutions, Inc.

File: B-407223.2

Date: December 13, 2012

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DIGEST

Agency unreasonably evaluated the protester's bid of an equal product under a brand name or equal solicitation conducted under simplified acquisition procedures where the solicitation lacked salient characteristics and the equal product was not shown to be significantly different from the brand name product.

DECISION

Veterans Healthcare Supply Solutions, Inc. (VHSS), of Jacksonville, Florida, protests the award by the Department of Veterans Affairs (VA) of a contract to Metro Medical Equipment & Supply, Inc., of St. Louis, Missouri, under FedBid[1] Buy No. VA248-12-R-1735 to provide five electrosurgical units.[2] VHHS argues that the agency unreasonably rejected its lower-priced product.

We sustain the protest.

[1] FedBid is a commercial online procurement services provider that runs a website at FedBid.com.

[2] Electrosurgery is the application of a high-frequency electric current to biological tissue as a means to cut, coagulate, desiccate, or fulgurate tissue.

BACKGROUND

The solicitation was issued on June 18, 2012, as a small business set-aside, brand name or equal requirement. The solicitation did not identify whether it was an invitation for bids or a request for quotations. Vendors were informed that "bids" would be ranked by price and "may" be evaluated using criteria other than price. Solicitation at 1. The solicitation also stated:

> **Brand Name or Equal:** The Buyer is allowing Sellers to submit bids for alternate items, provided those items meet all of the salient physical, functional, or performance characteristics specified by this solicitation. Sellers MUST enter exactly what they are bidding (including make, model and description) into the blank description field in order for the bid to be considered. The Buyer will evaluate 'equal' items on the basis of information furnished by the Seller or identified in the bid and reasonably available to the Buyer. The Buyer is not responsible for locating or obtaining any information not identified in the Bid.

Id.

The solicitation listed 18 contract line items (CLIN). CLIN 001 specified the electrosurgical unit identified as Product Number 10140-100, VIO300D, manufactured by ERBE Elektromedizin GmbH. CLINs 002-016 specified associated equipment identified by ERBE product numbers, and CLINs 017 and 018 specified warranties. The solicitation did not contain or make reference to any salient characteristics of the identified brand name products.

The agency received three bids on June 29, including bids from Metro Medical, which distributes ERBE products, and VHSS, which distributes US Medical Innovations, LLC (USMI) products. Metro Medical offered the brand name product with a bid of $212,469.44. VHSS's bid of $126,175 offered the Argon Plasma Generator model SS-601MCa electrosurgical unit manufactured by USMI. VHHS represented that its product was "equal" to the brand name product.

With its bid, VHSS included descriptive information about the model SS-601MCa, including a picture of the USMI product as well as product literature that highlighted various features of its product. The bid also included a chart titled "Electrosurgical Units Comparison List," which compared various features of ERBE Model VIO300D to USMI's model SS-601MCa. Also included with VHSS's bid was a "Section 510(k) Summary" for the USMI model SS-601MCa prepared by USMI for the Food and

Drug Administration (FDA).[3] The 510(k) summary listed six "predicate devices" to USMI's product, including ERBE's Model VIO300D, and stated:

> **Comparison to Predicate Devices:**
>
> These devices are equivalent in intended use, technological characteristics, and performance characteristics to the named predicate devices.

Protest, Tab 4, 510(k) Summary (Apr. 6, 2011), at 2. VHSS's bid also included a letter from FDA to USMI, which stated the following:

> We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent . . .to [the] legally marketed predicate devices.

Protest, Tab 4, FDA Letter to USMI (Apr. 6, 2011), at 1.

The agency rejected VHSS's bid, finding that it did not offer an equal product, and made award to Metro Medical. This protest followed.

ANALYSIS

VHSS protests that the VA unreasonably determined that its offered product was not equal to the brand name product.

Federal Acquisition Regulation (FAR) § 11.104 allows the use of brand name or equal purchase descriptions in describing agency needs in a solicitation, including those conducted under FAR Parts 12 and 13, but requires:

> (b) Brand name or equal purchase descriptions must include, in addition to the brand name, a general description of those salient physical, functional, or performance characteristics of the brand name item that an 'equal' item must meet to be acceptable for award. Use brand name or equal descriptions when the salient characteristics are firm requirements.

FAR § 11.104(b). Thus, this brand name or equal solicitation was defective because it did not identify salient characteristics, so that bidders offering equal products were left to guess at the desired essential qualities of the brand-name

[3] The terminology is based upon the relevant section 510(k) of the Federal Food, Drug, and Cosmetics Act, which is codified at 21 U.S.C. § 360(k) (2006).

item. See Ciba Corning Diagnostics Corp., B-223131, Aug. 13, 1986, 86-2 CPD ¶ 185 at 3. We have recognized that where, as here, an agency does not include a list of salient characteristics in a brand name or equal solicitation, the agency is precluded from rejecting a bid offering an equal product for noncompliance with some performance or design feature, unless the offered item is significantly different from the brand-name product. Id. at 4; Elementar Americas, Inc., B-289115, Jan. 11, 2002, 2002 CPD ¶ 20 at 2.

VHHS's bid literature was evaluated by two doctors and a nurse manager employed by the VA, who determined that the USMI product was not equal to the brand name product. The first and primary reason that the VA determined that USMI's product was not equal to the brand name product was the agency's determination that USMI's electrosurgical unit uses constant power, where power stays constant as the device cuts through all tissue types. Agency Report (AR) at 3; see Hearing Transcript (Tr.) at 18.[4] The brand name electrosurgical unit uses constant voltage. Id. The agency stated the following regarding the issue of constant voltage versus constant power electrosurgical units:

> If voltage is constant then, as resistance rises, current falls off. The current level must be high at the start of the cut to establish the electrical arcs needed to cut tissue. As the cut proceeds, the current should decrease. However, with constant power devices, similar to Protester's, the voltage variation that accompanies these factors can cause excessive coagulation (thermal injury). This is a significant, patient safety issue.

AR at 3. The evaluator testified that because of this constant voltage feature the ERBE electrosurgical unit "gives us an incremental cutting action, rather than one cutting action," which results in a "very controlled cut." Tr. at 18-19.

VHSS responded to the VA's evaluation both in writing and at the hearing convened by our Office. As set forth below, the VA has not refuted, or shown to be in error, the protester's assertions that its product is, in fact, equal to the specified product. For example, the protester notes that its proposed USMI model SS-601MCa electrosurgical unit utilizes a Tissue Impedance Sensitive Control (TISC), which senses the impedance in tissue and keeps the selected power constant as it cuts through all tissue types, and that the USMI product is therefore not significantly different from the brand name product. Tr. at 104, 112, 117. The TISC system was specifically mentioned in VHHS's descriptive literature. Protest, Tab 4, VHSS Bid, at 13.

[4] Our Office convened a hearing in this matter where the agency provided as a witness one of the evaluators.

Also included in VHSS's bid is a chart titled "Electrosurgical Units Comparison List," which compares certain features of ERBE Model V10 300 D to USMI's model SS-601MCa, wherein it is stated that USMI's product included the "TISC System [which] keeps selected power constant with all tissue types, including those with high impedance." Protest, Tab 4, VHSS Bid, at 5. The submitted product literature also indicates that USMI's electrosurgical device offers four pulse, or fractionated cuts, called E-cuts, that coagulates the tissue and cuts it at the same time, which VHSS claims, is functionally similar to the pertinent feature in the the brand name ERBE unit. Id.; Tr. at 96-97, 126. Thus, the record suggests that the proposed USMI electrosurgical unit has similar capabilities to those of the ERBE brand name unit in this respect and is thus not significantly different.

The record also shows that the agency may have discounted the information in VHSS's bid because the VA's evaluators were not familiar with USMI's electrosurgical unit. The record shows that the evaluators compared ERBE's electrosurgical unit, which uses constant voltage, to the constant power electrosurgical units that it currently uses; the currently used units are much older and the agency was seeking to replace them. Tr. at 19-20, 31, 46-47. The evaluator/witness stated that his evaluation of the products was based on his personal experience with the ERBE unit, and that his lack of familiarity and experience with the USMI unit prevented him from being able to evaluate it. Tr. at 44-45. Based on this record, we cannot find that the agency reasonably determined that USMI's electrosurgical unit was significantly different from the brand name unit because of this power feature.

The second reason that the agency determined that USMI's unit was not equal to the brand name unit had to do with the location of the filter and whether it would be changed after each use. The brand name ERBE electrosurgical unit includes a filter on the catheter or probe that would be changed after each use. Tr. at 21. The evaluation summary stated:

> On the USMI comparison chart, listed as 'inside equipment.' Not expressly stated whether it could be changed with each patient as desired by department and recommended by SGNA (Society for Gastrointestinal Nurses and Associates)

Contracting Officer's Statement at 2.

The record also does not establish that the lack of an outside filter that would be changed after each use in USMI's unit makes it significantly different from the ERBE brand name unit. The VA evaluator/witness was unfamiliar with the SGNA recommendation, but stated the agency desired a filter on the probe that would be changed after each use due to a cross-contamination incident that occurred in a VA facility in Miami, Florida. Tr. at 62. However, the protester provided unrebutted evidence that the incident in Miami arose from the VA's improper sterilization of

reused scopes, rather than any issue with the filter. Tr. at 137; Protester's Post-Hearing Comments at 8; exh. H. VA Inspector General's Report (June 16, 2009).

Moreover, the USMI witness testified that changing the internal filter after each use of USMI's electrosurgical unit was unnecessary, and that its filter need only be changed once a year. Tr. at 99-100, 133, 138-43. The VA evaluator/witness, who was not familiar with the USMI unit, assumed that all filters on electrosurgical units needed to be changed after each use to avoid cross-contamination. Tr. at 24, 44-45, 60.

Finally, as noted above, USMI provided with its bid a copy of the section 501(k) letter from FDA stating that the USMI electrosurgical unit was substantially equivalent to the ERBE device based on the summary that had been provided. Protest, Tab 4, FDA Letter to USMI (Apr. 6, 2011), at 1. While the VA evaluator/witness discounted the relevance of this FDA approval, Tr. at 35-36, he also admitted his unfamiliarity with the section 501(k) process and did not know that the brand name product was designated a predicate device for the USMI model SS-601MCa offered by VHSS. Tr. at 74-75.

While our Office affords particular deference to the technical expertise of agency personnel where their technical judgments involve matters of human life and safety, Sig Sauer, Inc., B-402339.3, July 23, 2010, 2010 CPD ¶ 184 at 2, the record before us does not withstand scrutiny. In short, in its written materials and in testimony presented at the hearing, the VA has not shown that VHSS's proposed USMI electrosurgical unit was significantly different from the brand name ERBE unit.

RECOMMENDATION

We recommend that the agency reevaluate these units, and determine and document whether the USMI device is significantly different from the brand name item. Alternatively, we recommend that the agency resolicit using a solicitation that identifies the characteristics in the brand name product that the VA views as salient characteristics, and evaluate the units against those requirements. We also recommend that VHSS be reimbursed the costs of filing and pursuing this protest, including reasonable attorney fees. 4 C.F.R. § 21.8(d)(1) (2012). VHSS should submit its certified claim for costs, detailing the time expended and cost incurred, directly to the contracting agency within 60 days after receipt of this decision. 4 C.F.R. § 21.8(f)(1).

The protest is sustained.

Susan A. Poling
General Counsel