Statement of Requirements

Pharmaceutical(s) and Med/ Surg

(Can be used for FSS)

DESCRIPTION:

ITEM # STS-GL-041 - G4 PLATINUM SENSOR; invasive(e.g. subcutaneous), disposable, for use with interstitial continuous glucose monitoring system

(Please check all blocks below that apply and submit in WORD format.)

FUNDING (Check one)

☒ VA FORM 2237 # 766-4-14-400-0517

☐ Funding memorandum

CONTRACT DELIVERY TERMS (Check all that apply)

☒ Deliver entire purchased amount within ___*10*_ days after award

☐ Deliver by means of multiple deliveries. (Identify number, date(s) after award and quantities for each deliver.)

_____
_____
_____
_____

☐ Deliver purchased amount to multiple delivery points. (Explain)

_____
_____
_____

PEDIGREE REQUIREMENTS Include: ☒ Yes ☐ No

Comments: _____

_____
_____

CONTRACT DURATION (check one)

☐ One time buy.

☐ Base + options. Explain duration (e.g. – 6 month base with 2 each 3 month options, etc.)

Describe: _____

_____

AS508 BAR CODING (MAY 2012) Include: ☒ **Yes** ☐ **No**

All pharmaceutical products provided under this contract shall include bar code labeling at the unit-of-use package level. The bar code labeling must be in a linear format that conforms to all GS1-128 (formerly EAN.UCC) or Health Industry Business Communication Council (HIBCC) Health Industry Bar Code (HIBC) supplier labeling standards. The bar code symbology must comply with all GSI or HIBCC parameters including, but not limited to: symbology type or encoded pattern, bar and space dimensions and tolerances, and allowable ratio of wide to narrow elements.

The bar code may be any linear bar code symbology such as GS1-128 (formerly EAN.UCC), GS1 Data Bar (formerly RSS), or Universal Product Code (if the UPC contains the National Drug Code or NDC). The bar code must encode the NDC, either alone or within the GS1 data structure (Global Trade Item Number (GTIN)).

The bar code printing must be American National Standards Institute (ANSI)/International Organization for Standardization (ISO)/IEC Quality Grade C or better. Manufacturers and packagers must ensure that production runs include an initial verification check, as well as routine audits to ensure the bar code is printed clearly and consistently to meet the quality standard of Grade C or better. Contractors shall be responsible for ensuring that bar code labels meet the quality requirements specified in this clause prior to shipping pharmaceutical products to any Government Prime Vendor or authorized ordering activity under this contract.

The bar code must be on the outside container or wrapper of the medication as well as on the immediate container, unless the bar code is readily visible and machine-readable through the outside container or wrapper. When the bar code is not easily machine-readable through the over wrap, the over wrap should contain the bar code.

The bar code must go on each cell of a blister pack. Furthermore, the bar code must remain intact under normal conditions of use; thus it should not be printed across the perforations of a blister pack.

When applicable to the symbology used, bar codes shall be surrounded by sufficient quiet zone so that the bar code can be scanned correctly. Bar code placement shall minimize curvature of the bar code.

For example, bar codes should be placed in "ladder orientation" on vials or bottles to minimize curvature of the bar code. Bar code labeling shall not be placed solely on outer packaging.

It is recommended that bar code labeling also include the lot number and expiration date. If two separate distinctive bar codes are used, one for NDC and the other for lot number/expiration date, the lot number and expiration date bar code must not be in close proximity to the NDC barcode or in a format that may be confused with the NDC bar code. When applicable, all Healthcare Distribution Management Association (HDMA) guidelines shall be followed.

AS1335 THERAPEUTIC EQUIVALENCE (FEB 2007) Include: ☒ **Yes** ☐ **No**

Only products that have received under the Federal Food, Drug and Cosmetic Act a therapeutic equivalence code of "A" by the Food and Drug Administration will be considered, unless all drugs in the family group are "B" rated. In that case, no award will be made other than to the innovator unless the non-innovator vendor submits acceptable data demonstrating bioequivalence.

AS1344 RECALLS (MAR 2009) Include: ☒ **Yes** ☐ **No**

If a drug recall is initiated for any drug provided under this contract, regardless of whether it is a voluntary recall by the manufacturer or a recall required by the U.S. Food and Drug Administration (FDA); or, if FDA withdraws their approval to manufacture any drug that is included on this contract, the following action shall immediately be taken by the contractor:

Forward two copies of the recall notification along with any pertinent information to:

1) _____
Attn:_____
_____
_____

2) _____
_____
_____
_____

AS1527 NATIONAL DRUG CODES (MAY 2009) Include: ☒ **Yes** ☐ **No**

Offerors shall provide a separate and distinct eleven-digit National Drug Code (NDC) number unique to the offeror (e.g., 00012-3456-78) for each product proposed, in the space provided following each item in Part I, "Schedule of Supplies and Prices" of the solicitation. The first five numbers of the eleven-digit NDC number for each product proposed shall identify the offeror. Offers that fail to provide the information required by this clause by the solicitation closing date shall be rejected and shall receive no further consideration.

AS7001 NOTICE TO DEALERS AND SUPPLIERS (FEB 2011) Include: ☒ **Yes** ☐ **No**

(a) If other than the manufacturer, the offeror shall submit either: (1) A letter of commitment from the manufacturer to the offeror which will assure the offeror of a source of supply sufficient to satisfy the Government's requirements for the contract period, **OR** (2) evidence that the offeror will have an uninterrupted source of supply from which to satisfy the Government's requirements for the contract period. If the offeror and its manufacturer are affiliates, the letter of commitment or evidence as required herein is required of the manufacturing facility, regardless of the relationship with the offeror. **Offers that fail to meet this requirement before contract award shall be rejected and shall receive no further consideration.**

(b) To be considered acceptable, the letter of commitment:

1) Shall be on the manufacturer's letterhead.
2) Shall be dated.
3) Shall reference the solicitation number and the product committed to manufacture.
4) Shall state that the manufacturer assures the offeror of an uninterrupted source of supply sufficient to satisfy the Government's requirements for the contract period, and that the manufacturer is currently manufacturing the product.
5) Shall be signed by an officer of the manufacturer's company (include printed name, title and telephone number).
6) Shall indicate source of product to include country of origin.

OTHER REQUIREMENTS (Check all that apply)

☐ Offerors must state the exact name of the drug being supplied as it will appear on the label. Offerors shall also provide a unique 11-digit NDC number for all items offered; the NDC number must be specific to the offering company and to the drug being supplied. Any package size ordered below 500 count will be considered to be for Unit of Use issue and will require a Safety/Child Proof cap. Glass bottles are not acceptable.

☒ The expiration dates of the pharmaceutical(s) are to be no less than ___12__ months from date of delivery.

☒ Any substitution of packaging sizes must be approved in writing by the Contracting Officer.

☒ Any change that deviates from the specific item requested must be approved by the Contracting Officer in writing. For example, the replacement of capsules for tablets or suspended action for extended release items will require approval beforehand.

☒ Partial deliveries of product will need to be approved in writing by the Contracting Officer.

☒ Minimal lot numbers of product is required. More than 3 lot numbers of product must be approved by the Contracting Officer in writing.

☒ Offered items must be end products that are U.S.-made or from designated countries in accordance with FAR 52.225-5, Trade Agreements. End products from any other country will not be considered unless no other acceptable offers are received.

☐ A minimum desired bottle size will be 100cc with a child safety type cap that does not exceed the diameter of the bottle. It must also have a cylindrical body and minimum of 5.75 inches circumference. Items packaged in a bottle smaller than 100cc will be considered but a positive cost adjustment per bottle of $0.6165 will be applied during price evaluation to each bottle to compensate for the cost to repackage in an adequately sized bottle to allow labeling.

☒ It is incumbent upon the offeror /contractor to initiate any actions requiring the approval of the contracting officer. Failure to obtain contracting officer approvals may result in rejection of offers or cancellation of award.

☒ Acceptance of any vendor-proposed NDC or UPC shall be contingent on CMOP approval.

☒ If a line item indicates more than one NDC/UPC, Vendor MUST specify which NDC/UPC is used when quoting. If offering an alternate, Vendor MUST indicate proposed alternate on the spreadsheet, in the column titled “VENDOR PROPOSED ALTERNATE NDC (PKG SZ)” and indicate bottle size in parentheses. ALL OFFERS SHOULD BE PRESENTED IN EXCEL FORMAT NOT A PDF.

☒ If the pre-approved alternate NDC is provided by the Vendor, and if the unit size is different from the original unit requested, then the Vendor must also adjust the final quantity accordingly, e.g.: 1 bottle @1000 to 10 bottles @ 100, noting the change.

☒ For reconciliation purposes, all shipments shall reference the original VA obligation/order number even if purchased product is from another partnered company.

☒ All shipments shall come with a packing slip identifying NDC, PRODUCTS, and LINE ITEM NUMBERS from the purchase order. Documentation shall include Vendor's point of contact for reporting noted discrepancies, damages, or incorrect product. Invoice price must match purchase order price. Failure to supply this information may cause a delay with payment.

☒ All like product shall be packaged and shipped together.

☒ Breakable items shall be packaged appropriately with blister pack or bubble wrap.

☒ Vendor shall provide a return authorization and pickup for any damaged products or incorrect products received within one week of request.

☒ If an offeror cannot deliver all product as ordered, the Government reserves the right to terminate for cause and award to the next-lowest bidder.

☐ Other terms:

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