|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT** | | | | | | | | | 1. CONTRACT ID CODE | | PAGES OF PAGES | | | |
| 1 | | 6 | |
| 2. AMENDMENT/MODIFICATION NO.  **Mass Modification 0006** | | | 3. EFFECTIVE DATE | | | 4. REQUISITION/PURCHASE REQ. NO. | | | | 5. PROJECT NO. *(If applicable)* | | | | |
| 6. ISSUED BY: CODE: | | | |  | | 7. ADMINISTERED BY *(If other than Item 6)* CODE: | | | | | |  | | |
| Department of Veterans Affairs  National Acquisition Center  P.O. Box 76, Bldg. 37  Hines, IL 60141 | | | | |  | | | | | | | | |
| 8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)* | | | | | | | (X) | 9A. AMENDMENT OF SOLICITATION NUMBER | | | | | | |
|
| 9B. DATED *(SEE ITEM 11)* | | | | | | |
|
| X | 10A. MODIFICATION OF CONTRACT/ORDER NUMBER | | | | | | |
| 10B. DATED *(SEE ITEM 13)* | | | | | | |
| CODE | | FACILITY CODE | | | | |
| 11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS | | | | | | | | | | | | | | |
| The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers  is extended  is not extended.  Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:  (a) By completing Items 8 and 15, and returning     copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted;  or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified. | | | | | | | | | | | | | | |
| 12. ACCOUNTING AND APPROPRIATION DATA *(If required)* | | | | | | | | | | | | | | |
| **13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS.**  **IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.** | | | | | | | | | | | | | | |
| (x) | A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A. | | | | | | | | | | | | | |
|  | B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office,* *appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b). | | | | | | | | | | | | | |
| X | C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:  52.212-4(c) Contract Terms and Conditions - Commercial Items (Changes) | | | | | | | | | | | | | |
|  | D. OTHER *(Specify type of modification and authority)* | | | | | | | | | | | | | |
| E. **IMPORTANT**: Contractor  is not,  is required to sign this document and return  1 copies to the issuing office. | | | | | | | | | | | | | | |

|  |
| --- |
| 14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*  **SOLICITATION REFRESHMENT**  This modification is issued to incorporate the attached regulations and special language changes and Scope of Solicitation into the above-referenced contract. These changes are the result of the June 2018 refreshment of 65 I B solicitation number M5-Q50A-03-R7 (now issued as M5-Q50A-03-R8). For the full text of added and updated regulations and special language, please select the “65 I B Pharmaceuticals” link in the word cloud on VA’s FSS web page at [www.fss.va.gov](http://www.fss.va.gov/). On the Schedule 65 I B web page you will find a solicitation link that will direct you to the refreshed solicitation files on FedBizOpps. |
| Except as provided herein, all terms and conditions of the document referenced in item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 15A. NAME AND TITLE OF SIGNER *(Type or print)* | | 16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)* | | |
| 15B. CONTRACTOR/OFFEROR  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *(Signature of person authorized to sign)* | 15C. DATE SIGNED | | 16B. UNITED STATES OF AMERICA  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *(Signature of Contracting Officer)* | 16C. DATE SIGNED |
| EXCEPTION TO SF 30 STANDARD FORM 30 (REV. 11/2016)  APPROVED BY OIRM 11-84 Prescribed by GSA FAR (48 CFR) 53.243 | | | | |

**Removed:**

#### 52.203-11 Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions (Sep 2007)

#### 52.203-12 Limitation on Payments to Influence Certain Federal Transactions (Oct 2010)

**52.203-15** Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (Jun 2010)

**52.209-11** Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law (Feb 2016)

**52.212-5** Contract Terms & Conditions Required to Implement Statutes or Executive Orders - Commercial Items (Alternate II – Oct 2015)

**52.222-1** Notice to the Government of Labor Disputes (Feb 1997)

**52.232-39** Unenforceability of Unauthorized Obligations (Jun 2013)

**552.238-76** Definition (Federal Supply Schedules) - Recovery Purchasing (Feb 2007)

**552.238-80** Use of Federal Supply Schedule Contracts by Certain Entities - Recovery Purchasing (Feb 2007)

**852.203-71** Display of Department of Veterans Affairs Hotline Poster (Dec 1992)

**852.219-71** VA Mentor-Protégé Program (Dec 2009)

**AS1508** Option to Extend the Term of the Contract (Mar 2005)

**CP-FSS-4-A** Solicitation Copies (Mar 1996, Tailored)

ACH Form

American Recovery and Reinvestment Act Program Participation

Supplemental Commercial Sales Practices

**Added:**

**52.203-19** Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017)

**52.204-21** Basic Safeguarding of Covered Contractor Information Systems (Jun 2016)

**52.204-22** Alternative Line Item Proposal (Jan 2017)

**52.207-6** Solicitation of Offers from Small Business Concerns and Small Business Teaming Arrangements or Joint Ventures (Multiple-Award Contracts) (Oct 2016)

**52.217-9** Option to Extend the Term of the Contract (Mar 2000)

**52.223-20** Aerosols (Jun 2016)

**52.223-21** Foams (Jun 2016)

**52.224-3** Privacy Training (Jan 2017)

**52.232-23** Assignment of Claims (May 2014)

**52.242-5** Payments to Small Business Subcontractors (Jan 2017)

**52.246-2** Inspection of Supplies – Fixed Price (Aug 1996)

**552.238-79** Use of Federal Supply Schedule Contracts by Non-Federal Entities (Jul 2016)

Alternate Contact for Contract Administration (Aug 2017)

Ordering Contact (Mar 2018)

Scope of Solicitation (Jun 2018)

Warranty and Return Goods Policy (Aug 2017)

**Updated/Revised:**

**52.204-7** System for Award Management (Oct 2016)

**52.204-10** Reporting Executive Compensation and First-Tier Subcontract Awards (Oct 2016)

**52.204-13** System for Award Management Maintenance (Oct 2016)

**52.204-16** Commercial and Government Entity Code Reporting (Jul 2016)

**52.204-18** Commercial and Government Entity Code Maintenance (Jul 2016)

**52.212-1** Instructions to Offerors - Commercial Items (Jan 2017)

**52.212-3** Offeror Representations and Certifications - Commercial Items (Nov 2017)

**52.212-4** Contract Terms and Conditions - Commercial Items (Jan 2017) (Tailored)

**52.212-5** Contract Terms & Conditions Required to Implement Statutes or Exec. Orders - Commercial Items (Jan 2018)

**52.216-22** Indefinite Quantity (Oct 1995)

**52.219-8** Utilization of Small Business Concerns (Nov 2016)

**52.219-9** Small Business Subcontracting Plan (Jan 2017, Alternate II – Nov 2016)

**52.219-14** Limitations on Subcontracting (Jan 2017)

**52.222-19** Child Labor - Cooperation with Authorities and Remedies (Oct 2016)

**52.222-26** Equal Opportunity (Sep 2016)

**52.223-11** Ozone-Depleting Substances and High Potential Hydrofluorocarbons (Jun 2016)

**52.225-5** Trade Agreements (Oct 2016)

**552.211-78** Commercial Delivery Schedule (Multiple Award Schedule) (Feb 1996, Tailored, Notes)

**552.211-89** Non-Manufactured Wood Package Material For Export (Jul 2016)

**552.212-71** Contract Terms and Conditions Applicable to GSA Acquisition of Commercial Items (Jun 2016)

**552.219-71** Notice to Offerors of Subcontracting Plan Requirements (Oct 2016, Tailored)

**552.219-72** Preparation, Submission, and Negotiation of Subcontracting Plans (Oct 2016, Tailored)

**552.238-71** Submission and Distribution of Authorized FSS Schedule Pricelists (Jul 2016, Tailored)

**552.238-74** Industrial Funding Fee and Sales Reporting (Jan 2016, Tailored)

**552.238-75** Price Reductions (Jul 2016)

**552.238-78** Scope of Contract (Eligible Ordering Activities) (Jul 2016, Tailored)

**552.238-81** Modification (Federal Supply Schedule) (Apr 2015, Alt I - Jun 2016, Tailored)

**A-FSS-11** Consideration of Offers under Standing Solicitation (Jan 2016, Tailored)

**AS212** Generic Item Modifications (Jun 2018)

**CP-FSS-2** Significant Changes (Oct 1988)

**CP-FSS-3** Notice: Requests for Explanation or Information (Mar 1996)

**CSP-1 (**Tailored, Notes – Aug 2017)

**F-FSS-202-G** Delivery Prices (Jan 1994, Note)

**G-FSS-900-C** Contact for Contract Administration (Jul 2003, Tailored)

**I-FSS-600** Contract Price Lists (Oct 2016, Tailored)

**I-FSS-644** Dealers and Suppliers (Oct 1988, Notes – Mar 2018)

Additional Discounts / Concessions Offered to the Government

Agent Authorization (Mar 2018)

Business Size Determination & NAICS Code Designation (Aug 2017)

Compliance Confirmation (Apr 2018)

Continuation of SF1449

Direct-To-Patient Distribution Program Participation (Apr 2018)

eOffer (Mar 2018)

Instructions for Pre-Award Review Process (Aug 2017)

Minimum Acceptable Order Proposal (Aug 2016)

Pricelist Proposal Preparation (Doc 03 Excel Spreadsheet)

Proposed Pricing – Required Format

SF1449

Signatory Authority (Aug 2017)

Small Business Subcontracting Plan (Aug 2017)

Utilization of Dealers/Distributors (Aug 2017)

**SCOPE OF** **SOLICITATION (JUN 2018)**

The Federal Supply Schedule (FSS) program is also known as the GSA Schedules Program or the Multiple Award Schedule (MAS) Program. The FSS program is directed and managed by GSA and provides Federal agencies with a simplified process for obtaining commercial supplies and services at prices associated with volume buying. Indefinite-delivery, indefinite quantity contracts are awarded to provide supplies and services at stated prices for given periods of time. GSA has delegated authority to the VA to manage the Schedules for medical supplies under the VA FSS program.

This solicitation is issued to establish contracts which may be used on a nonmandatory basis by eligible users, as a source of supply for the supplies or services described herein, for domestic and/or overseas delivery. At a minimum, contract holders are required to deliver their products within the 48 contiguous states, Alaska, Hawaii, Puerto Rico, Washington, DC, and U.S. territories. Domestic delivery also includes a port or consolidation point, within the aforementioned areas, for orders received from overseas activities. Offerors who cannot provide the required geographic coverage will not be considered for award. This solicitation further requires that offered prices cover delivery to destinations (i.e. F.O.B. destination) located within the 48 contiguous states and the District of Columbia. Offerors can choose whether or not prices cover delivery f.o.b. destination to Alaska, Hawaii, and the Commonwealth of Puerto Rico. Additionally, the solicitation defines the number of calendar days after receipt of order (ARO) within which delivery must be made.

**Special Item Numbers (SINs):** FSS solicitations set forth broad categories of accepted products/services, referred to as Special Item Numbers (SINs), listed in the Continuation of SF1449 in Vendor Response Document 02. Offerors are not required to submit their entire catalog of products/services but are free to choose which items they will offer as long as those items fall within one of the solicitation’s pre-defined SIN categories. Items that do not fall within one of these SINs are considered to be out of scope of the solicitation and cannot be awarded. An item’s acceptability under the schedule may be further restricted by the Trade Agreements Act, limitations on certain types of commercial items, and a determination of fair and reasonable pricing.

**Additional Product Restrictions:** Please note that the scope of this schedule is further limited by the following:

* **Drug Supply Chain Security Act (DSCSA):** The contractor shall follow all appropriate requirements as implemented in the Drug Supply Chain Security Act (DSCSA), including all applicable traceability and licensing requirements.
* **FDA Regulatory Requirements:** Offered products shall be in compliance with all applicable U.S. Food and Drug Administration (FDA) regulations and requirements, including but not limited to bar code labeling, therapeutic equivalence, new drug applications (NDA) or abbreviated NDA (ANDA), labeler codes, National Drug Codes (NDC), and Good Manufacturing Practices (GMP). Products not in compliance with applicable regulations and requirements will not be considered for award under this solicitation.
* **Drugs:** All items classified as drugs by the FDA must have an NDA, ANDA, or comply with an approved monograph.
* **Natural/Homeopathic Products:** FSS will not award under this schedule any items considered to be herbal/bontanical supplements, natural or homeopathic remedies unless FDA approved as evidenced by an NDA, ANDA, or compliance with an approved monograph.
* **Dietary Supplements / Vitamins:** Vitamins are permitted on schedule as dietary supplements provided that they meet all the requirements of the Dietary Supplement Health and Education Act (DSHEA) and FDA regulations. Manufacturers and distributors are prohibited from marketing products that are adulterated or misbranded and are responsible for evaluating the safety and labeling of their products before marketing to ensure that they meet all DSHEA and FDA regulations.
* **Nutritional Supplements / Medical Foods:** Only items meeting the FDA’s definition of medical food will be permitted on schedule as a nutritional supplement. A medical food, as defined in section 5(b)(3) of the Orphan Drug Act, 21 USC 360ee(b)(3), is “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.” Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition.
* **EXCEPTIONS:** Exceptions to the above listed restrictions may be made based on medical need, facility demand, and evidence based clinical reasons.

**New Items vs. Refurbished or “Grey Market Goods”**

This solicitation is for the award of new items only. The Contractor shall provide only new equipment and new parts for the required products described herein. Absolutely no “grey market goods” or refurbished products shall be provided under any delivery order. Grey market goods are defined as genuine branded goods sold outside of an authorized sales-territory (or by non-authorized dealers in an authorized territory) at prices lower than being charged in authorized sales territories (or by authorized dealers). All equipment must be covered by the manufacturer’s warranty.

**Trade Agreements Act**

The [Trade Agreements Act](https://www.acquisition.gov/far/html/Subpart%2025_4.html) is applicable to all Schedules. Except as noted below regarding certain items under SIN 42-2a, **ONLY** US-made or designated country end products shall be awarded to responsible VA FSS contractors. It is the offeror’s responsibility to verify that all offered products are U.S. made or [designated country](https://www.va.gov/oal/business/fss/taa.asp) end products as defined in clause FAR 52.225-5. When an item consists of components from various countries and the components are assembled in an additional country, the test to determine country of origin is “substantial transformation” (see [FAR 25.001(c)(2)](https://www.acquisition.gov/far/html/Subpart%2025_1.html)). Offerors requiring a determination on substantial transformation can go to the US Customs and Border Protection (CBP) [Office of Regulations and Rulings](https://www.cbp.gov/trade/rulings). Please note that CBP has issued decisions regarding pharmaceuticals which determined that the location where substantial transformation took place was the source of the Active Pharmaceutical Ingredient (API) and not the location where the product was mixed, measured and formulated.

**Trade Agreements Act – Non-Availability Determination *-*** Special Item Number 42-2A product items (single source drug, innovator multiple source drug, and any biological product identified under Section 600.3 of Title 21, CFR) that are not substantially transformed in the U.S. or a designated country under 52.225-5 Trade Agreements must be included in the offeror’s proposal to obtain a Federal Supply Schedule 65IB contract and listed as other end products as required by 52.212-3(g)(5)(ii). Offerors of these items must complete the Trade Agreements Act Non-Availability Determination Request located within this document.

**Commercial Items - Limitations**

Per GSA regulations at 538.271(a), MAS awards are for commercial items as defined in FAR 2.101. Certain types of “custom” items fall under this definition as modified commercial items. For example, FSS accepts configurable items, such as configurable wheelchairs, and custom count items, such as pharmaceutical tablets packaged in quantities specifically for the Government. FSS, however, has made a business decision not to award contracts for the following:

* Custom Packs
* Non-Configurable Custom Products Made to Individual Specifications, including, but not limited to, such items as custom orthotics, custom dental products, and prescription eyeglasses.

Additionally, per the commercial item definition at FAR 2.101, FSS cannot award contracts to installation, maintenance, and repair service companies who do not also provide similar services to the general public (i.e. Government only service providers).

**Notice of Additional Requirements - Ordering Level**

In addition to the terms and conditions set forth in this solicitation, the contractor may, in the performance of orders issued under this contract, be responsible for further requirements at the ordering level. For more information on these potential, additional requirements, please see the note in Solicitation Document 01 after FAR clause 52.216-18 Ordering.

**Please note** that the VA does not promote the use of any company’s specific Schedule contract. Vendors should be aware that obtaining a VA Schedule contract is **not a guarantee of sales**. Vendors awarded a VA Schedule contract will need to [market](http://www.gsa.gov/portal/content/104176) their supplies and services to Government customers as they would to commercial customers. A listing of eligible schedule users can be found at on GSA’s website at <http://gsa.federalschedules.com/resources/eligible-gsa-schedule-users/>