SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS
OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30

1. REQUISITION NO.

PAGE 1 OF 99

2. CONTRACT NO.	3. AWARD/EFFECTIVE DATE	4. ORDER NO.	5. SOLICITATION NUMBER	6. SOLICITATION ISSUE DATE
			VA258-15-R-0592	07/27/2015

7. FOR SOLICITATION INFORMATION CALL:	a. NAME	b. TELEPHONE NO. (No Collect Calls)	8. OFFER DUE DATE/LOCAL TIME
	Steve Turner	602-795-4435	08-10-2015 3 PM

9. ISSUED BY CODE

Department of Veterans Affairs
VISN/18PHX
777 E. Missouri, Suite 300
Phoenix AZ 85014

10. THIS ACQUISITION IS
- [X] UNRESTRICTED OR [ ] SET ASIDE: _____ % FOR:
- [ ] SMALL BUSINESS
- [ ] HUBZONE SMALL BUSINESS
- [ ] SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS
- [ ] WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM
- [ ] EDWOSB
- [ ] 8(A)

NAICS: 325412

SIZE STANDARD: 750 Employees

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED	12. DISCOUNT TERMS	13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	13b. RATING	14. METHOD OF SOLICITATION
[ ] SEE SCHEDULE	N/A	[ ]	N/A	[ ] RFQ [ ] IFB [X] RFP

15. DELIVER TO CODE

Department of Veterans Affairs
VISN/18PHX
777 E. Missouri, Suite 300

Phoenix AZ 85014

16. ADMINISTERED BY CODE

Department of Veterans Affairs
VISN/18PHX
777 E. Missouri, Suite 300
Phoenix AZ 85014

17a. CONTRACTOR/OFFEROR CODE FACILITY CODE

TELEPHONE NO. DUNS: DUNS+4:

[ ] 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18a. PAYMENT WILL BE MADE BY CODE

Department of Veterans Affairs
FMS-VA-FSC
PO Box 149971
Austin TX 78714-9971

PHONE: FAX:

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED
[ ] SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
0001	Provide Formulation and Batch Records Pharmaceutical In Accordance with the attached Statement of Work and Price Schedule. See attached. Period of Performance: 1 Base Year and 4 Option Years (Use Reverse and/or Attach Additional Sheets as Necessary)				

25. ACCOUNTING AND APPROPRIATION DATA

26. TOTAL AWARD AMOUNT (For Govt. Use Only)

[X] 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA [ ] ARE [X] ARE NOT ATTACHED.

[ ] 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA [ ] ARE [ ] ARE NOT ATTACHED

[ ] 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED

[ ] 29. AWARD OF CONTRACT: REF. _____ OFFER DATED _____. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR		31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER)	
30b. NAME AND TITLE OF SIGNER (TYPE OR PRINT)	30c. DATE SIGNED	31b. NAME OF CONTRACTING OFFICER (TYPE OR PRINT)	31c. DATE SIGNED

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SECTION B - CONTINUATION OF SF 1449 BLOCKS

B.1 CONTRACT ADMINISTRATION DATA

(continuation from Standard Form 1449, block 18A.)

1. Contract Administration: All contract administration matters will be handled by the following individuals:

a. CONTRACTOR:

b. GOVERNMENT: Contracting Officer 00258

Department of Veterans Affairs

VISN/18PHX

777 E. Missouri, Suite 300

Phoenix AZ 85014

2. CONTRACTOR REMITTANCE ADDRESS: All payments by the Government to the contractor will be made in accordance with:

[X] 52.232-34, Payment by Electronic Funds Transfer—Other Than System For Award Management, or
[] 52.232-36, Payment by Third Party

3. INVOICES: Invoices shall be submitted in arrears:

a. Quarterly []

b. Semi-Annually []

c. Other []

4. GOVERNMENT INVOICE ADDRESS: All Invoices from the contractor shall be submitted electronically in accordance with VAAR Clause 852.232-72 Electronic Submission of Payment Requests.

Department of Veterans Affairs

FMS-VA-FSC

PO Box 149971

Austin TX 78714-9971

ACKNOWLEDGMENT OF AMENDMENTS: The offeror acknowledges receipt of amendments to the Solicitation numbered and dated as follows:

AMENDMENT NO	DATE

B.2 LIMITATIONS ON SUBCONTRACTING-- MONITORING AND COMPLIANCE (JUN 2011)

This solicitation includes FAR 52.219-4 Notice of Price Evaluation Preference for HubZone Small Business Concerns. Accordingly, any contract resulting from this solicitation will include this clause. The contractor is advised in performing contract administration functions, the CO may use the services of a support contractor(s) retained by VA to assist in assessing the contractor's compliance with the limitations on subcontracting or percentage of work performance requirements specified in the clause. To that end, the support contractor(s) may require access to contractor's offices where the contractor's business records or other proprietary data are retained and to review such business records regarding the contractor's compliance with this requirement. All support contractors conducting this review on behalf of VA will be required to sign an “Information Protection and Non-Disclosure and Disclosure of Conflicts of Interest Agreement” to ensure the contractor's business records or other proprietary data reviewed or obtained in the course of assisting the CO in assessing the contractor for compliance are protected to ensure information or data is not improperly disclosed or other impropriety occurs. Furthermore, if VA determines any services the support contractor(s) will perform in assessing compliance are advisory and assistance services as defined in FAR 2.101, Definitions, the support contractor(s) must also enter into an agreement with the contractor to protect proprietary information as required by FAR 9.505-4, obtaining access to proprietary information, paragraph (b). The contractor is required to cooperate fully and make available any records as may be required to enable the CO to assess the contractor's compliance with the limitations on subcontracting or percentage of work performance requirement.

(End of Clause)

B.3 SUBCONTRACTING COMMITMENTS--MONITORING AND COMPLIANCE (JUN 2011)

This solicitation includes VAAR 852.215-70, Service-Disabled Veteran-Owned and Veteran-Owned Small Business Evaluation Factors, and VAAR 852.215-71, Evaluation Factor Commitments. Accordingly, any contract resulting from this solicitation will include these clauses. The contractor is advised in performing contract administration functions, the CO may use the services of a support contractor(s) to assist in assessing contractor compliance with the subcontracting commitments incorporated into the contract. To that end, the support contractor(s) may require access to the contractor's business records or other proprietary data to review such business records regarding contract compliance with this requirement. All support contractors conducting this review on behalf of VA will be required to sign an “Information Protection and Non-Disclosure and Disclosure of Conflicts of Interest Agreement” to ensure the contractor's business records or other proprietary data reviewed or obtained in the course of assisting the CO in assessing the contractor for compliance are protected to ensure information or data is not improperly disclosed or other impropriety occurs. Furthermore, if VA determines any services the support contractor(s) will perform in assessing compliance are advisory and assistance services as defined in FAR 2.101, Definitions, the support contractor(s) must also enter into an agreement with the contractor to protect proprietary information as required by FAR 9.505-4, obtaining access to proprietary information, paragraph (b). The contractor is required to cooperate fully and make available any records as may be required to enable the CO to assess the contractor compliance with the subcontracting commitments.

(End of Clause)

B.4 PRICE SCHEDULE OF SUPPLIES.

FY15 Base Year						
Task	**CLIN No.**	**Product**	**Est. Qty**	**Unit**	**Unit Price**	**Estimated Amount**
Task 1	0001	Provide an active capsule formulation containing *one* active ingredient (API) and excipients. The API is contained in commercial product. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0002	Provide an active capsule formulation containing one API and excipients. The API is contained in commercial product. *The API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a simple report that summarizes the work performed.	1	each		
	0003	Provide an active capsule formulation containing one API and excipients. The API is contained in commercial product. *The API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0004	Provide an active capsule formulation containing *two* or more APIs and excipients. The API is contained in commercial	1	each		

		product. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a simple report that summarizes the work performed.				
	0005	Provide an active capsule formulation containing two or more APIs and excipients. The API is contained in commercial product. *The API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0006	Provide an active capsule formulation containing two or more APIs and excipients. The API is contained in commercial product. *The API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0007	Provide an active capsule formulation made from milled or ground commercial tablets: Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that	1	each		

		summarizes the work performed.				
	0008	Provide an active capsule formulation made from milled or ground tablets. *API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0009	Provide an active capsule formulation made from milled or ground tablets. *API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0010	Provide an excipient filled placebo capsule formulation to “match” a powder filled capsule containing an API or a commercial capsule. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential product formulations include: • Powder filled placebo capsule to be similar to a Size 2 Vancomycin capsule	1	each		
	0011	Provide a formulation for over-encapsulation of either an active or placebo tablet or capsule. Determine the excipients to fill	2	each		

		space in capsule bottom around product encapsulated. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential product formulations include: • Size 2 Vancomycin capsule or placebo capsule overencapsulated in a size 0 capsule • Fidaxomycin tablet (caplet) overencapsulated in a size 0 capsule				
	0012	Provide a formulation for over-encapsulation of either an active or placebo tablet or capsule. Determine the excipients to fill space in capsule bottom around product encapsulated. *API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0013	Provide a formulation for over-encapsulation of either an active or placebo tablet or capsule. Determine the excipients to fill space in capsule bottom around product encapsulated. *API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that	1	each		

		summarizes the work performed.				
	0014	Provide an active tablet formulation containing one API. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential products required in the base year: • 100 mg, Allopurinol tablet • 300 mg Allopurinol tablet • 400 mg Allopurinol tablet	3	each		
	0015	Provide an active tablet formulation containing one API. *API is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0016	Provide an active tablet formulation containing one API. *API is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0017	Provide an active tablet formulation containing *two* or more APIs in the product. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”.	1	each		

		Provide a summary report that summarizes the work performed.				
	0018	Provide an active tablet formulation containing *two* or more APIs in the product. *API is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0019	Provide an active tablet formulation containing *two* or more APIs in the product. *API is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0020	Provide a placebo tablet formulation. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential products required in the base year: • 40 mg febuxostat placebo tablet • 80 mg febuxostat placebo tablet • 100 mg Allopurinol placebo tablet • 300 mg Allopurinol placebo tablet	5	each		

		• 400 mg Allopurinol placebo tablet				
	0021	Provide a formulation for an aqueous based coating for active or placebo tablets or capsules. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed. • 40 mg febuxostat (Takeda Uloric) placebo tablet • 80 mg febuxostat (Takeda Uloric) placebo tablet	2	each		
	0022	Provide a formulation for an aqueous based coating formulation for active tablets or capsules. The tablet or capsule to be coated is *hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	0023	Provide a formulation for an aqueous based coating formulation for active tablets or capsules. The tablet or capsule to be coated is *a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	0024	Provide an aqueous based coating formulation for active tablets or capsules using coating with Modified Release properties. The release profile for the drug will be defined in conjunction with the	1	each		

		CSPCRPCC Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	0025	Provide an aqueous based coating formulation for active or placebo tablets or capsules using coating with Modified Release properties *Active tablet or capsule is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0026	Provide an aqueous based coating formulation for active or placebo tablets or capsules using coating with Modified Release properties *Active tablet or capsule is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0027	Provide a formulation for an oral, liquid. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0028	Provide a formulation for an oral,	1	each		

		liquid. Evaluate information necessary to provide formulation. *The liquid is hazardous.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	0029	Provide a formulation for an oral, liquid. Evaluate information necessary to provide formulation. *The liquid is a controlled substance.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	30	Provide a formulation for an oral, liquid containing two or more active ingredients. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
Task 2	31	Provide a formulation for an oral, liquid containing two or more active ingredients. Evaluate information necessary to provide formulation. *The liquid is hazardous.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	32	Provide a formulation for an oral, liquid containing two or more active ingredients.	1	each		

		Evaluate information necessary to provide formulation. *The liquid is a controlled substance.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	33	Provide a formulation for an oral, non-aqueous liquid, typically something like Vitamin E filled in a hard gelatin capsule. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0034	Provide a formulation for an oral, non-aqueous liquid, typically something like Vitamin E filled in a hard gelatin capsule. *The non-aqueous liquid is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0035	Provide a formulation for an oral, non-aqueous liquid, typically something like Vitamin E filled in a hard gelatin capsule. *The non-aqueous liquid is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that	1	each		

		summarizes the work performed.				
Task 3	0036	Provide a revision to a formulation (i.e. to overcome pilot batch, processing, stability, content uniformity issues) Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0037	Provide a revision to a formulation (i.e. to overcome pilot batch, processing, stability, content uniformity issues) *Active tablet or capsule is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	0038	Provide a revision to a formulation (i.e. to overcome pilot batch, processing, stability, content uniformity issues) *Active tablet or capsule is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
Task 4	0039	Fill approximately 600 capsules or make tablets following the formulation to provide the Center with capsules or tablets or oral liquid product to conduct product method transfer and stability	1	each		

		testing.				
	0040	Fill approximately 600 capsules or make tablets following the formulation to provide the Center with capsules or tablets or oral liquid product to conduct product method transfer and stability testing. *The non-aqueous liquid is hazardous.*	1	each		
	0041	Fill approximately 600 capsules or make tablets following the formulation to provide the Center with capsules or tablets or oral liquid product to conduct product method transfer and stability testing. *The non-aqueous liquid is a controlled substance.*	1	each		
TOTAL ESTIMATED BASE YEAR COST						

FY16 Option Year 1						
Task	**CLIN No.**	**Product**	**Est. Qty**	**Unit**	**Unit Price**	**Estimated Amount**
Task 1	1001	Provide an active capsule formulation containing *one* active ingredient (API) and excipients. The API is contained in commercial product. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1002	Provide an active capsule formulation containing one API and excipients. The API is contained in commercial product. *The API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the	1	each		

		formulation that includes the items described under “Batch Record”. Provide a simple report that summarizes the work performed.				
	1003	Provide an active capsule formulation containing one API and excipients. The API is contained in commercial product. *The API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	1004	Provide an active capsule formulation containing *two* or more APIs and excipients. The API is contained in commercial product. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a simple report that summarizes the work performed.	1	each		
	1005	Provide an active capsule formulation containing two or more APIs and excipients. The API is contained in commercial product. *The API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that	1	each		

		summarizes the work performed.				
	1006	Provide an active capsule formulation containing two or more APIs and excipients. The API is contained in commercial product. *The API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1007	Provide an active capsule formulation made from milled or ground commercial tablets: Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1008	Provide an active capsule formulation made from milled or ground tablets. *API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1009	Provide an active capsule formulation made from milled or ground tablets. *API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the	1	each		

		formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	1010	Provide an excipient filled placebo capsule formulation to “match” a powder filled capsule containing an API or a commercial capsule. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential product formulations include: • Powder filled placebo capsule to be similar to a Size 2 Vancomycin capsule	1	each		
	1011	Provide a formulation for over-encapsulation of either an active or placebo tablet or capsule. Determine the excipients to fill space in capsule bottom around product encapsulated. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential product formulations include: • Size 2 Vancomycin capsule or placebo capsule overencapsulated in a size 0 capsule • Fidaxomycin tablet	2	each		

		(caplet) overencapsulated in a size 0 capsule				
	1012	Provide a formulation for over-encapsulation of either an active or placebo tablet or capsule. Determine the excipients to fill space in capsule bottom around product encapsulated. *API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1013	Provide a formulation for over-encapsulation of either an active or placebo tablet or capsule. Determine the excipients to fill space in capsule bottom around product encapsulated. *API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1014	Provide an active tablet formulation containing one API. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed. Potential products required in the base year: • 100 mg, Allopurinol	3	each		

		tablet • 300 mg Allopurinol tablet • 400 mg Allopurinol tablet				
	1015	Provide an active tablet formulation containing one API. *API is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1016	Provide an active tablet formulation containing one API. *API is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1017	Provide an active tablet formulation containing *two* or more APIs in the product. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		

	1018	Provide an active tablet formulation containing *two* or more APIs in the product. *API is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1019	Provide an active tablet formulation containing *two* or more APIs in the product. *API is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1020	Provide a placebo tablet formulation. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed. Potential products required in the base year: • 40 mg febuxostat placebo tablet • 80 mg febuxostat placebo tablet • 100 mg Allopurinol placebo tablet • 300 mg Allopurinol placebo tablet • 400 mg Allopurinol	5	each		

		placebo tablet				
	1021	Provide a formulation for an aqueous based coating for active or placebo tablets or capsules. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed. • 40 mg febuxostat (Takeda Uloric) placebo tablet • 80 mg febuxostat (Takeda Uloric) placebo tablet	2	each		
	1022	Provide a formulation for an aqueous based coating formulation for active tablets or capsules. The tablet or capsule to be coated is *hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1023	Provide a formulation for an aqueous based coating formulation for active tablets or capsules. The tablet or capsule to be coated is *a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1024	Provide an aqueous based coating formulation for active tablets or capsules using coating with	1	each		

		Modified Release properties. The release profile for the drug will be defined in conjunction with the CSPCRPCC Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.				
	1025	Provide an aqueous based coating formulation for active or placebo tablets or capsules using coating with Modified Release properties *Active tablet or capsule is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1026	Provide an aqueous based coating formulation for active or placebo tablets or capsules using coating with Modified Release properties *Active tablet or capsule is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1027	Provide a formulation for an oral, liquid. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the	1	each		

		items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	1028	Provide a formulation for an oral, liquid. Evaluate information necessary to provide formulation. *The liquid is hazardous.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	1029	Provide a formulation for an oral, liquid. Evaluate information necessary to provide formulation. *The liquid is a controlled substance.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	1030	Provide a formulation for an oral, liquid containing two or more active ingredients. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
Task 2	1031	Provide a formulation for an oral, liquid containing two or more active ingredients. Evaluate information necessary to provide formulation. *The liquid is hazardous.*	1	each		

		Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	1032	Provide a formulation for an oral, liquid containing two or more active ingredients. Evaluate information necessary to provide formulation. *The liquid is a controlled substance.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	1033	Provide a formulation for an oral, non-aqueous liquid, typically something like Vitamin E filled in a hard gelatin capsule. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	1034	Provide a formulation for an oral, non-aqueous liquid, typically something like Vitamin E filled in a hard gelatin capsule. *The non-aqueous liquid is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		

TASK 3	1035	Provide a formulation for an oral, non-aqueous liquid, typically something like Vitamin E filled in a hard gelatin capsule. *The non-aqueous liquid is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1036	Provide a revision to a formulation (i.e. to overcome pilot batch, processing, stability, content uniformity issues) Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1037	Provide a revision to a formulation (i.e. to overcome pilot batch, processing, stability, content uniformity issues) *Active tablet or capsule is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	1038	Provide a revision to a formulation (i.e. to overcome pilot batch, processing, stability, content uniformity issues) *Active tablet or capsule is a*	1	each		

		controlled substance. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.				
Task 4	1039	Fill approximately 600 capsules or make tablets following the formulation to provide the Center with capsules or tablets or oral liquid product to conduct product method transfer and stability testing.	1	each		
	1040	Fill approximately 600 capsules or make tablets following the formulation to provide the Center with capsules or tablets or oral liquid product to conduct product method transfer and stability testing. *The non-aqueous liquid is hazardous.*	1	each		
	1041	Fill approximately 600 capsules or make tablets following the formulation to provide the Center with capsules or tablets or oral liquid product to conduct product method transfer and stability testing. *The non-aqueous liquid is a controlled substance.*	1	each		
TOTAL ESTIMATED OPTION YEAR 1 COST						

FY17 Option Year 2						
Task	**CLIN No.**	**Product**	**Est. Qty**	**Unit**	**Unit Price**	**Estimated Amount**
Task 1	2001	Provide an active capsule formulation containing *one* active ingredient (API) and excipients. The API is contained in commercial product. Evaluate information necessary to provide formulation.	1	each		

		Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	2002	Provide an active capsule formulation containing one API and excipients. The API is contained in commercial product. *The API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a simple report that summarizes the work performed.	1	each		
	2003	Provide an active capsule formulation containing one API and excipients. The API is contained in commercial product. *The API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	2004	Provide an active capsule formulation containing *two* or more APIs and excipients. The API is contained in commercial product. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a simple report that summarizes the work performed.	1	each		

	2005	Provide an active capsule formulation containing two or more APIs and excipients. The API is contained in commercial product. *The API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	2006	Provide an active capsule formulation containing two or more APIs and excipients. The API is contained in commercial product. *The API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	2007	Provide an active capsule formulation made from milled or ground commercial tablets: Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	2008	Provide an active capsule formulation made from milled or ground tablets. *API is hazardous* Evaluate information necessary to	1	each		

		provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.				
	2009	Provide an active capsule formulation made from milled or ground tablets. *API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	2010	Provide an excipient filled placebo capsule formulation to "match" a powder filled capsule containing an API or a commercial capsule. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed. Potential product formulations include: • Powder filled placebo capsule to be similar to a Size 2 Vancomycin capsule	1	each		
	2011	Provide a formulation for over-encapsulation of either an active or placebo tablet or capsule. Determine the excipients to fill space in capsule bottom around product encapsulated. Evaluate information necessary to	2	each		

		provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential product formulations include: • Size 2 Vancomycin capsule or placebo capsule overencapsulated in a size 0 capsule • Fidaxomycin tablet (caplet) overencapsulated in a size 0 capsule				
	2012	Provide a formulation for over-encapsulation of either an active or placebo tablet or capsule. Determine the excipients to fill space in capsule bottom around product encapsulated. *API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	2013	Provide a formulation for over-encapsulation of either an active or placebo tablet or capsule. Determine the excipients to fill space in capsule bottom around product encapsulated. *API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that	1	each		

		summarizes the work performed.				
	2014	Provide an active tablet formulation containing one API. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed. Potential products required in the base year: • 100 mg, Allopurinol tablet • 300 mg Allopurinol tablet • 400 mg Allopurinol tablet	3	each		
	2015	Provide an active tablet formulation containing one API. *API is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	2016	Provide an active tablet formulation containing one API. *API is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	2017	Provide an active tablet formulation containing *two* or more APIs in the product. Evaluate information necessary to	1	each		

		provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	2018	Provide an active tablet formulation containing *two* or more APIs in the product. *API is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	2019	Provide an active tablet formulation containing *two* or more APIs in the product. *API is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	2020	Provide a placebo tablet formulation. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential products required in the base year:	5	each		

		• 40 mg febuxostat placebo tablet • 80 mg febuxostat placebo tablet • 100 mg Allopurinol placebo tablet • 300 mg Allopurinol placebo tablet • 400 mg Allopurinol placebo tablet				
	2021	Provide a formulation for an aqueous based coating for active or placebo tablets or capsules. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed. • 40 mg febuxostat (Takeda Uloric) placebo tablet • 80 mg febuxostat (Takeda Uloric) placebo tablet	2	each		
	2022	Provide a formulation for an aqueous based coating formulation for active tablets or capsules. The tablet or capsule to be coated is *hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	2023	Provide a formulation for an aqueous based coating formulation for active tablets or capsules. The tablet or capsule to be coated is *a controlled substance.* Evaluate information necessary to provide formulation.	1	each		

		Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	2024	Provide an aqueous based coating formulation for active tablets or capsules using coating with Modified Release properties. The release profile for the drug will be defined in conjunction with the CSPCRPCC Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	2025	Provide an aqueous based coating formulation for active or placebo tablets or capsules using coating with Modified Release properties *Active tablet or capsule is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	2026	Provide an aqueous based coating formulation for active or placebo tablets or capsules using coating with Modified Release properties *Active tablet or capsule is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch	1	each		

		Record". Provide a summary report that summarizes the work performed.				
	2027	Provide a formulation for an oral, liquid. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	2028	Provide a formulation for an oral, liquid. Evaluate information necessary to provide formulation. *The liquid is hazardous.* Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	2029	Provide a formulation for an oral, liquid. Evaluate information necessary to provide formulation. *The liquid is a controlled substance.* Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	2030	Provide a formulation for an oral, liquid containing two or more active ingredients. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch	1	each		

		Record”. Provide a summary report that summarizes the work performed.				
Task 2	2031	Provide a formulation for an oral, liquid containing two or more active ingredients. Evaluate information necessary to provide formulation. *The liquid is hazardous.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	2032	Provide a formulation for an oral, liquid containing two or more active ingredients. Evaluate information necessary to provide formulation. *The liquid is a controlled substance.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	2033	Provide a formulation for an oral, non-aqueous liquid, typically something like Vitamin E filled in a hard gelatin capsule. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	2034	Provide a formulation for an oral, non-aqueous liquid, typically something like Vitamin E filled in a hard gelatin capsule. *The non-aqueous liquid is*	1	each		

		hazardous. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	2035	Provide a formulation for an oral, non-aqueous liquid, typically something like Vitamin E filled in a hard gelatin capsule. *The non-aqueous liquid is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
TASK 3	2036	Provide a revision to a formulation (i.e. to overcome pilot batch, processing, stability, content uniformity issues) Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	2037	Provide a revision to a formulation (i.e. to overcome pilot batch, processing, stability, content uniformity issues) *Active tablet or capsule is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the	1	each		

		formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	2038	Provide a revision to a formulation (i.e. to overcome pilot batch, processing, stability, content uniformity issues) *Active tablet or capsule is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
Task 4	2039	Fill approximately 600 capsules or make tablets following the formulation to provide the Center with capsules or tablets or oral liquid product to conduct product method transfer and stability testing.	1	each		
	2040	Fill approximately 600 capsules or make tablets following the formulation to provide the Center with capsules or tablets or oral liquid product to conduct product method transfer and stability testing. *The non-aqueous liquid is hazardous.*	1	each		
	2041	Fill approximately 600 capsules or make tablets following the formulation to provide the Center with capsules or tablets or oral liquid product to conduct product method transfer and stability testing. *The non-aqueous liquid is a controlled substance.*	1	each		
TOTAL ESTIMATED OPTION YEAR 2 COST						

FY18 Option Year 3						
Task	**CLIN No.**	**Product**	**Est. Qty**	**Unit**	**Unit Price**	**Estimated Amount**
Task 1	3001	Provide an active capsule formulation containing *one* active ingredient (API) and excipients. The API is contained in commercial product. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	3002	Provide an active capsule formulation containing one API and excipients. The API is contained in commercial product. *The API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a simple report that summarizes the work performed.	1	each		
	3003	Provide an active capsule formulation containing one API and excipients. The API is contained in commercial product. *The API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	3004	Provide an active capsule formulation containing *two* or more APIs and excipients. The API is contained in commercial	1	each		

		product. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a simple report that summarizes the work performed.				
	3005	Provide an active capsule formulation containing two or more APIs and excipients. The API is contained in commercial product. *The API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	3006	Provide an active capsule formulation containing two or more APIs and excipients. The API is contained in commercial product. *The API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	3007	Provide an active capsule formulation made from milled or ground commercial tablets: Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the	1	each		

		items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	3008	Provide an active capsule formulation made from milled or ground tablets. *API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	3009	Provide an active capsule formulation made from milled or ground tablets. *API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	3010	Provide an excipient filled placebo capsule formulation to “match” a powder filled capsule containing an API or a commercial capsule. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential product formulations include: • Powder filled placebo	1	each		

		capsule to be similar to a Size 2 Vancomycin capsule				
	3011	Provide a formulation for over-encapsulation of either an active or placebo tablet or capsule. Determine the excipients to fill space in capsule bottom around product encapsulated. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential product formulations include: • Size 2 Vancomycin capsule or placebo capsule overencapsulated in a size 0 capsule • Fidaxomycin tablet (caplet) overencapsulated in a size 0 capsule	2	each		
	3012	Provide a formulation for over-encapsulation of either an active or placebo tablet or capsule. Determine the excipients to fill space in capsule bottom around product encapsulated. *API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	3013	Provide a formulation for over-encapsulation of either an active or placebo tablet or capsule. Determine the excipients to fill space in capsule bottom around product encapsulated.	1	each		

		API is a controlled substance Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	3014	Provide an active tablet formulation containing one API. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential products required in the base year: • 100 mg, Allopurinol tablet • 300 mg Allopurinol tablet • 400 mg Allopurinol tablet	3	each		
	3015	Provide an active tablet formulation containing one API. *API is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	3016	Provide an active tablet formulation containing one API. *API is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch	1	each		

		Record". Provide a summary report that summarizes the work performed.				
	3017	Provide an active tablet formulation containing *two* or more APIs in the product. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	3018	Provide an active tablet formulation containing *two* or more APIs in the product. *API is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	3019	Provide an active tablet formulation containing *two* or more APIs in the product. *API is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	3020	Provide a placebo tablet formulation.	5	each		

		Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential products required in the base year: • 40 mg febuxostat placebo tablet • 80 mg febuxostat placebo tablet • 100 mg Allopurinol placebo tablet • 300 mg Allopurinol placebo tablet • 400 mg Allopurinol placebo tablet				
	3021	Provide a formulation for an aqueous based coating for active or placebo tablets or capsules. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. • 40 mg febuxostat (Takeda Uloric) placebo tablet • 80 mg febuxostat (Takeda Uloric) placebo tablet	2	each		
	3022	Provide a formulation for an aqueous based coating formulation for active tablets or capsules. The tablet or capsule to be coated is *hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch	1	each		

		Record". Provide a summary report that summarizes the work performed.				
	3023	Provide a formulation for an aqueous based coating formulation for active tablets or capsules. The tablet or capsule to be coated is *a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	3024	Provide an aqueous based coating formulation for active tablets or capsules using coating with Modified Release properties. The release profile for the drug will be defined in conjunction with the CSPCRPCC Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	3025	Provide an aqueous based coating formulation for active or placebo tablets or capsules using coating with Modified Release properties *Active tablet or capsule is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		

	3026	Provide an aqueous based coating formulation for active or placebo tablets or capsules using coating with Modified Release properties *Active tablet or capsule is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	3027	Provide a formulation for an oral, liquid. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	3028	Provide a formulation for an oral, liquid. Evaluate information necessary to provide formulation. *The liquid is hazardous.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	3029	Provide a formulation for an oral, liquid. Evaluate information necessary to provide formulation. *The liquid is a controlled substance.* Provide a batch record for the formulation that includes the items described under “Batch Record”.	1	each		

		Provide a summary report that summarizes the work performed.				
	3030	Provide a formulation for an oral, liquid containing two or more active ingredients. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
Task 2	3031	Provide a formulation for an oral, liquid containing two or more active ingredients. Evaluate information necessary to provide formulation. *The liquid is hazardous.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	3032	Provide a formulation for an oral, liquid containing two or more active ingredients. Evaluate information necessary to provide formulation. *The liquid is a controlled substance.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	3033	Provide a formulation for an oral, non-aqueous liquid, typically something like Vitamin E filled in a hard gelatin capsule. Evaluate information necessary to provide formulation. Provide a batch record for the	1	each		

		formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	3034	Provide a formulation for an oral, non-aqueous liquid, typically something like Vitamin E filled in a hard gelatin capsule. *The non-aqueous liquid is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	3035	Provide a formulation for an oral, non-aqueous liquid, typically something like Vitamin E filled in a hard gelatin capsule. *The non-aqueous liquid is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
TASK 3	3036	Provide a revision to a formulation (i.e. to overcome pilot batch, processing, stability, content uniformity issues) Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		

	3037	Provide a revision to a formulation (i.e. to overcome pilot batch, processing, stability, content uniformity issues) *Active tablet or capsule is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	3038	Provide a revision to a formulation (i.e. to overcome pilot batch, processing, stability, content uniformity issues) *Active tablet or capsule is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
Task 4	3039	Fill approximately 600 capsules or make tablets following the formulation to provide the Center with capsules or tablets or oral liquid product to conduct product method transfer and stability testing.	1	each		
	3040	Fill approximately 600 capsules or make tablets following the formulation to provide the Center with capsules or tablets or oral liquid product to conduct product method transfer and stability testing. *The non-aqueous liquid is hazardous.*	1	each		
	3041	Fill approximately 600 capsules or make tablets following the	1	each		

		formulation to provide the Center with capsules or tablets or oral liquid product to conduct product method transfer and stability testing. *The non-aqueous liquid is a controlled substance.*				
TOTAL ESTIMATED OPTION YEAR 3 COST						

FY19 Option Year 4						
Task	**CLIN No.**	**Product**	**Est. Qty**	**Unit**	**Unit Price**	**Estimated Amount**
Task 1	4001	Provide an active capsule formulation containing *one* active ingredient (API) and excipients. The API is contained in commercial product. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	4002	Provide an active capsule formulation containing one API and excipients. The API is contained in commercial product. *The API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a simple report that summarizes the work performed.	1	each		
	4003	Provide an active capsule formulation containing one API and excipients. The API is contained in commercial product. *The API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record".	1	each		

		Provide a summary report that summarizes the work performed.				
	4004	Provide an active capsule formulation containing *two* or more APIs and excipients. The API is contained in commercial product. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a simple report that summarizes the work performed.	1	each		
	4005	Provide an active capsule formulation containing two or more APIs and excipients. The API is contained in commercial product. *The API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	4006	Provide an active capsule formulation containing two or more APIs and excipients. The API is contained in commercial product. *The API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under "Batch Record". Provide a summary report that summarizes the work performed.	1	each		
	4007	Provide an active capsule formulation made from milled or ground commercial tablets: Evaluate information necessary to	1	each		

		provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	4008	Provide an active capsule formulation made from milled or ground tablets. *API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4009	Provide an active capsule formulation made from milled or ground tablets. *API is a controlled substance* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4010	Provide an excipient filled placebo capsule formulation to “match” a powder filled capsule containing an API or a commercial capsule. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential product formulations include: • Powder filled placebo capsule to be similar to a	1	each		

		Size 2 Vancomycin capsule				
	4011	Provide a formulation for over-encapsulation of either an active or placebo tablet or capsule. Determine the excipients to fill space in capsule bottom around product encapsulated. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential product formulations include: • Size 2 Vancomycin capsule or placebo capsule overencapsulated in a size 0 capsule • Fidaxomycin tablet (caplet) overencapsulated in a size 0 capsule	2	each		
	4012	Provide a formulation for over-encapsulation of either an active or placebo tablet or capsule. Determine the excipients to fill space in capsule bottom around product encapsulated. *API is hazardous* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4013	Provide a formulation for over-encapsulation of either an active or placebo tablet or capsule. Determine the excipients to fill space in capsule bottom around product encapsulated. *API is a controlled substance* Evaluate information necessary to	1	each		

		provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	4014	Provide an active tablet formulation containing one API. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential products required in the base year: • 100 mg, Allopurinol tablet • 300 mg Allopurinol tablet • 400 mg Allopurinol tablet	3	each		
	4015	Provide an active tablet formulation containing one API. *API is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4016	Provide an active tablet formulation containing one API. *API is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4017	Provide an active tablet formulation containing *two* or more APIs in the product.	1	each		

		Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	4018	Provide an active tablet formulation containing *two* or more APIs in the product. *API is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4019	Provide an active tablet formulation containing *two* or more APIs in the product. *API is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4020	Provide a placebo tablet formulation. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. Potential products required in the base year: • 40 mg febuxostat placebo tablet	5	each		

		• 80 mg febuxostat placebo tablet • 100 mg Allopurinol placebo tablet • 300 mg Allopurinol placebo tablet • 400 mg Allopurinol placebo tablet				
	4021	Provide a formulation for an aqueous based coating for active or placebo tablets or capsules. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed. • 40 mg febuxostat (Takeda Uloric) placebo tablet • 80 mg febuxostat (Takeda Uloric) placebo tablet	2	each		
	4022	Provide a formulation for an aqueous based coating formulation for active tablets or capsules. The tablet or capsule to be coated is *hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4023	Provide a formulation for an aqueous based coating formulation for active tablets or capsules. The tablet or capsule to be coated is *a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		

	4024	Provide an aqueous based coating formulation for active tablets or capsules using coating with Modified Release properties. The release profile for the drug will be defined in conjunction with the CSPCRPCC Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4025	Provide an aqueous based coating formulation for active or placebo tablets or capsules using coating with Modified Release properties *Active tablet or capsule is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4026	Provide an aqueous based coating formulation for active or placebo tablets or capsules using coating with Modified Release properties *Active tablet or capsule is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4027	Provide a formulation for an oral, liquid. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items	1	each		

		described under “Batch Record”. Provide a summary report that summarizes the work performed.				
	4028	Provide a formulation for an oral, liquid. Evaluate information necessary to provide formulation. *The liquid is hazardous.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4029	Provide a formulation for an oral, liquid. Evaluate information necessary to provide formulation. *The liquid is a controlled substance.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4030	Provide a formulation for an oral, liquid containing two or more active ingredients. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
Task 2	4031	Provide a formulation for an oral, liquid containing two or more active ingredients. Evaluate information necessary to provide formulation. *The liquid is hazardous.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that	1	each		

		summarizes the work performed.				
	4032	Provide a formulation for an oral, liquid containing two or more active ingredients. Evaluate information necessary to provide formulation. *The liquid is a controlled substance.* Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4033	Provide a formulation for an oral, non-aqueous liquid, typically something like Vitamin E filled in a hard gelatin capsule. Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4034	Provide a formulation for an oral, non-aqueous liquid, typically something like Vitamin E filled in a hard gelatin capsule. *The non-aqueous liquid is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4035	Provide a formulation for an oral, non-aqueous liquid, typically something like Vitamin E filled in a hard gelatin capsule. *The non-aqueous liquid is a controlled substance.* Evaluate information necessary to provide formulation.	1	each		

		Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.				
Task 3	4036	Provide a revision to a formulation (i.e. to overcome pilot batch, processing, stability, content uniformity issues) Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4037	Provide a revision to a formulation (i.e. to overcome pilot batch, processing, stability, content uniformity issues) *Active tablet or capsule is hazardous.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
	4038	Provide a revision to a formulation (i.e. to overcome pilot batch, processing, stability, content uniformity issues) *Active tablet or capsule is a controlled substance.* Evaluate information necessary to provide formulation. Provide a batch record for the formulation that includes the items described under “Batch Record”. Provide a summary report that summarizes the work performed.	1	each		
Task 4	4039	Fill approximately 600 capsules or make tablets following the	1	each		

		formulation to provide the Center with capsules or tablets or oral liquid product to conduct product method transfer and stability testing.				
	4040	Fill approximately 600 capsules or make tablets following the formulation to provide the Center with capsules or tablets or oral liquid product to conduct product method transfer and stability testing. *The non-aqueous liquid is hazardous.*	1	each		
	4041	Fill approximately 600 capsules or make tablets following the formulation to provide the Center with capsules or tablets or oral liquid product to conduct product method transfer and stability testing. *The non-aqueous liquid is a controlled substance.*	1	each		
TOTAL ESTIMATED COST OPTION YR 4						

OVERALL TOTAL ESTIMATED COST FOR BASE PLUS 4 YEARS__$_____

B.5

STATEMENT OF WORK

1. CONTRACT TITLE.
Provision of Clinical Trial Product Formulations and Batch Records (FBR) ***Five (5) year IDIQ contract*** firm fixed price contract for each CLIN.

2. BACKGROUND.
The Department of Veterans Affairs Cooperative Studies Program Clinical Research Pharmacy coordinating Center (CSPCRPCC) manufactures tablets, capsules and other oral dose products for Veteran patients to consume when participating in clinical trials.

The CSPCRPCC does not have the in-house expertise to define the Clinical Trial Formulations and Batch Records (FBR) for the products we manufacture. Thus we need to hire an organization with this expertise that will provide us with the FBR for each product.

3. SCOPE.

The CSPRPCC needs a five (5) year IDIQ contract with firm, fixed pricing for each CLIN for purchasing clinical trial FBRs. The IDIQ allows flexibility in the number of FBRs purchased, flexibility in ordering the FBRs after the requirements materialize, and they limit the Government's obligation to the minimum quantity specified in the contract.

The scope of work includes:

- ***Providing FBRs to the CSPCRPCC to use to manufacture*** placebo tablets,
- ***Providing FBRs to the CSPCRPCC to use to manufacture*** placebo capsules,
- ***Providing FBRs s to the CSPCRPCC to use to manufactur***e capsules containing one or more Active Pharmaceutical Ingredients (API)
- ***Providing FBRs to the CSPCRPCC to use to manufacture*** tablets containing one or more APIs
- ***Providing FBRs to the CSPCRPCC to use to coat*** tablets
- ***Providing FBRs to the CSPCRPCC to use to overencapsulate*** capsules or tablets containing active ingredients
- ***Providing FBRs to the CSPCRPCC to use to overencapsulate*** placebo tablets or capsules.

FBRs for new chemical entities will not be covered under this agreement. The work covered by this contract involves well characterized products that are commercially available. They may involve providing the FBR for a product in a different dosage form or strength than is commercially available. For example 100 mg and 300 mg Allopurinol products are commercially available. There may be a requirement for providing FBRs for 100 mg, 300 mg and a 400 mg Allopurinol tablet. The 400 mg tablet is not commercially available.

The work could involve products that are controlled substances or hazardous. The CSPCRPCC will not handle materials more hazardous than those with an exposure limit of $10<100\ \mu g/m^3$.

Over the last five years the CSPCRPCC has required from one to eight FBRs each year. The requirements vary each year depending on:
a. The clinical trials funded,

b. The clinical trial requirements to manufacture or not manufacture drug products.
c. The types of drug products that need to be manufactured,
d. The number of different drug products that need to be manufactured to meet each clinical trial's requirements.

Formulations
The various types of FBRs that may be required are listed in this SOW under Section 3 Schedule of Supplies.

Batch Records
The contractor will use the CSPRPCC batch record templates for each type of product manufacture, i.e. manufacture of a placebo tablet, manufacture of a capsule with API.

Samples of batch records which are representative of those used by the CSPCRPCC are provided in Exhibits 1 to 5 as follows:

Exhibit 1 – Placebo Tablets
Exhibit 2 – Coating Tablets
Exhibit 3 – Active Capsule Filling on Bosch
Exhibit 4 – Capsule Filling on the Ultra 8II
Exhibit 5 - Tablet Over-encapsulation on the Ultra 8II
Exhibit 6- Manufacturing Equipment

Items the batch records currently need to include are:

Batch Record Type	Requirements
Tablet Manufacture	The batch record shall include: • The equipment to use including the blender, sieve sizes, etc. • The range for the theoretical batch size. This is based on the requirements of the study and the blender used. • The raw materials, components or ingredients • The percentage of each raw material, component or ingredient in each tablet • The target tablet weight, thickness and hardness • The quantity by weight of each ingredient in each tablet • The tolerances for the tablet weight, thickness, hardness and for each ingredient • The step by step procedures for manufacturing the tablet, including the order of addition of raw material, blend time, sieving, etc. as required.
Tablet or Capsule Coating	The batch record shall include: • The appropriate coating pan to use. • The range for the theoretical batch size. This is based on the requirements of the study and the coater to be used. • The components or ingredients • The percentage of each component or ingredient required to coat each tablet • The target tablet weight gain (i.e. 3%) • The quantity by weight of each ingredient that will be added to each tablet • The step by step procedures for mixing the coating and applying it to the tablet or capsule, including items such as mixing time,

	recommended inlet temperature, air volume, pan speed, pan pressure, pan jog, pump speed, atomizing air and spray gun pattern air.
Capsule Manufacture	The batch record shall include: • The blender to use. (NOTE: some placebo capsules may use only one ingredient. The powder would not be blended. It would be gravity filled into the capsules). • The range for the theoretical batch size. This is based on the requirements of the study and the blender to be used. • The components or ingredients • The percentage of each component or ingredient in each capsule • The capsule that will be used • The target powder fill weight • The tolerances for the fill weight and for each ingredient • The quantity by weight of each ingredient in each capsule • The step by step procedures for manufacturing the capsule, including items such as blend time, sieving. • Recommended tamping pin size • Recommended dosing bowl height • Recommended compression setting
Over-encapsulation – Ultra 8II	The batch record shall include: • The blender to use if needed. Capsules containing overencapsulated product may be filled with one excipient that will not require blending. • The range for the theoretical batch size. This is based on the requirements of the study. • The components or ingredients • The percentage of each component or ingredient in each capsule • The capsule that will be used • The tolerances for the fill weight for each ingredient • The target weight of the finished capsule • The step by step procedures for overencapsulating the capsule or tablet.

Based upon changing requirements at the CSPRPCC, audit findings, International Standards Organization (ISO), FDA and other regulatory agency expectations, the contents of the batch record will change over time. These changes will be communicated to the contractor by the CSPRPCC in a timely manner so the contractor may incorporate them into batch records provided after the changes are made.

Equipment

The FBRs must be developed to utilize the CSPCRPCC manufacturing equipment. A list of equipment owned by the CSPCRPCC is found in:

Exhibit 6 – Manufacturing Equipment

The equipment list will be modified over time when equipment is replaced or new equipment is added. The CSPRPCC will work with the contractor to assure they are made aware of all new or obsoleted equipment.

Reports:
The contractor will be expected to provide a summary report of the work.

Other:

The Contractor will not provide FBR utilizing equipment other than that owned by the CSPCRPCC.

4. SPECIFIC TASKS.

The formulation development work should consist of one or more of the following tasks each year.

4.1 Task 1 – CLINS 1 – 30. Provide FBR and Summary Report

4.1.1 Subtask 1 – Evaluate Formulation Information – Contractor will evaluate literature for commercial product when available and/or evaluate literature available applicable to the product. Contractor will evaluate properties of the API such as crystal structure or shape, water and/or oxygen sensitivity, etc. Contractor will evaluate appropriate raw materials to use by looking at raw materials contained in commercial product when available, evaluating raw materials appropriate to the product, evaluating raw materials normally stocked by the CSPCRPCC, etc.

4.1.2 Subtask 2 – Provide FBR – Contractor will provide the CSPCRPCC with the FBR which will include, but not be limited to: the equipment to use, the range for the theoretical batch size, the raw materials to use in the formulation, the amount of each raw material to use, the amount of API to use in the formulation, the percentage of each material in the formulation, the physical specifications for the product being made (i.e. in-process and finished product weight, thickness, and hardness specification ranges and targets for tablets) the step by step instructions for making each product, the order of addition of raw materials, blend time, sieving, etc.

4.1.3 Subtask 3 – Report. – Contractor will provide the CSPRPCC with a summary report of the work conducted for each FBR provided.

4.1.4 Task 2 – CLINS 31 – 33. Provide Samples. Contractor will provide the CSPCRPCC with 600 capsules or tablets made using the formulation for evaluation.

4.2 Task 3 – CLINS 36 - 38. Formulation Revision.

4.2.1 Subtask 1 – Evaluate Formulation Information. If a formulation revision is required, the contractor will evaluate the original formulation, the equipment and

other information as required to improve the formulation so that it allows the CSPCRPCC to manufacture products that meet the requirements.

4.2.2 Subtask 2 – Provide FBR – Contractor will provide the CSPCRPCC with the revised FBR which include the changes required to make the product so that it meets the specifications.

4.2.3 Subtask 3 – Provide a Summary Report - Contractor will provide the CSPRPCC with a summary report of the work conducted for each revised FBR provided.

4.3 Task 4 – CLINS 39 – 41. Provide Samples. Contractor will provide the CSPCRPCC with 600 capsules or tablets made using the formulation(s) for evaluation.

5. PERFORMANCE MONITORING.

The CSPCRPCC will monitor performance by conducting periodic phone calls with the contractor when FBR work is ongoing. Product quality will be verified on receipt by manufacturing and testing product made with the FBR and by analyzing the summary report.

6. SECURITY REQUIREMENTS.

The C&A requirements do not apply. A Security Accreditation Package is not required

7. GOVERNMENT-FURNISHED EQUIPMENT (GFE)/GOVERNMENT-FURNISHED INFORMATION (GFI).

The following items may be provided to the contractor to fulfill the requirements:

a. Small quantities of Active Pharmaceutical Ingredient
b. Small quantities of raw materials such as starch, cellulose and other ingredients
c. Small quantities of capsules
d. One or two sets of tablet tooling
e. Product information such as preferred batch sizes
f. Product specifications such as drug strength for active tablets
g. Samples of tablets, capsules or other oral products for which we will make similar placebo products or active products

8. OTHER PERTINENT INFORMATION OR SPECIAL CONSIDERATIONS.

The contractor providing the FBRs must use individuals to perform the work with demonstrated experience developing solid oral dosage form products (tablets and capsules) for clinical trials regulated by FDA, the EU and other international regulatory agencies.

The contractor should have demonstrated experience providing FBRs for the equipment owned by the CSPCRPCC. The contractor should be available to respond to questions essentially immediately regarding the FBR if problems arise during manufacturing or testing.

a. Identification of Possible Follow-on Work.
Possible Follow-on-Work would be for FBRs not covered under this contract such as products using new chemical entities. Such a contract is not expected.

b. Identification of Potential Conflicts of Interest (COI).
No organizational Conflict of Interest exists.

c. Identification of Non-Disclosure Requirements.

The contractor will not have access to sensitive or proprietary information. The FBRs will not contain proprietary information.

d. Packaging, Packing and Shipping Instructions.
Product shall be shipped from the manufacturer to the attention of:

Jan Hickey
VA – CSPCRPCC
2401 Centre Avenue SE
Albuquerque, NM 87106
U.S.A.

505-248-3203

Shipments are accepted from 7:30 a.m. to 3:30 p.m. local time.
Tablets or capsules shall be shipped in appropriate containers to prevent contamination, degradation or shipping damage.

e. Inspection and Acceptance Criteria.
The CSPCRPCC will evaluate the Product delivered by:

- Reviewing the FBRs provided,
- Manufacturing pilot or other batches of product using the FBR provided,
- Testing the product the CSPCRPCC manufactures using the FBR to assure it meets the requirements.
- Testing the 600 tablets or capsules, if requested.
- Reviewing the Summary report.

9. RISK CONTROL.

The CSPCRPCC will minimize risk to Veteran patients taking drug products manufactured using the FBR provided under this contract by:

1. Manufacturing the product using the FBR provided.
2. Testing all product manufactured to assure it meets the in-process and finished product specifications.
3. Entering all process and product deviations, out of specification results, etc. into our Corrective and Preventive Action (CAPA) system, reviewing and correcting these items, documenting all changes appropriately and completing other actions as required to assure the products are safe.

10. PLACE OF PERFORMANCE.

The work will be performed at the Contractor's facilities.

11. PERIOD OF PERFORMACE.

Start Date	August 31, 2015	August 30, 2016
Option Year 1	August 31, 2016	August 30, 2017
Option Year 2	August 31, 2017	August 30, 2018
Option Year 3	August 31, 2018	August 30, 2019
Option Year 4	August 31, 2019	August 30, 2020

12. DELIVERY SCHEDULE.

SOW Task #	Deliverable Title	Format	Number	Calendar Days After CO Start& IDIQ Request Made
1	CLINS 1-30, Subtask 2 - Provide FBR	Electronic copy	1	15 days after request made unless multiple requests made on same date. Dates then to be staggered with first request completed within 15 days, and additional requests received every 7 days after that or as negotiated depending on complexity of request. The CSPRPCC will prioritize the requests.
1	CLINS 1-30, Subtask 3 - Report	Electronic copy	1	45 days after request made unless multiple requests made on same date. Dates then to be staggered with first request completed within 45 days, and additional requests received 30 days from delivery of the applicable FBR to the CSPCRPCC. The CSPRPCC will prioritize the requests.
2	**CLINS 31 – 33. Provide Samples.**	As required by product to be manufactured	600 each	35 days
3	**CLINS 36-38 Formulation Revision**	Electronic Copy	1Each	Not Applicable
4	**CLINS 39-41 Provide Samples**	Tablets or Capsules	600 Each	Not Applicable

13. ACRONYMS.

A. **CO** – Contracting Officer. The Federal employee who is warranted by the Government to enter into contracts on behalf of the Government and is the only person authorized to make changes to those contracts.

B. **COR** – Contracting Officer's Representative. Individual designated by the CO to place orders, furnish technical guidance, advice, certify invoices, and provide general supervision of the work performed under the executed contract.

C. **CSPCRPCC** – Cooperative Studies Program Clinical Research Pharmacy Coordinating Center.

D. **FBR -** Clinical Trial Formulations and Batch Records

E. **FDA** – Food and Drug Administration

F. **IDIQ** – Indefinite Delivery, Indefinite Quantity

G. **VAMC** – Department of Veterans Affairs Medical Center

H. **NMAHCS** – New Mexico Veterans Affairs Healthcare Sys

SECTION C - CONTRACT CLAUSES

C.1 52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS—COMMERCIAL ITEMS (MAY 2015)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Dec 2014)

(2) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(3) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[X] (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).

[] (2) 52.203-13, Contractor Code of Business Ethics and Conduct (APR 2010)(41 U.S.C. 3509).

[] (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (JUN 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

[X] (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Jul 2013) (Pub. L. 109-282) (31 U.S.C. 6101 note).

[] (5) [Reserved]

[] (6) 52.204-14, Service Contract Reporting Requirements (JAN 2014) (Pub. L. 111-117, section 743 of Div. C).

[] (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (JAN 2014) (Pub. L. 111-117, section 743 of Div. C).

[X] (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Aug 2013) (31 U.S.C. 6101 note).

[] (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Jul 2013) (41 U.S.C. 2313).

[] (10) [Reserved]

[] (11)(i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (NOV 2011) (15 U.S.C. 657a).

[] (ii) Alternate I (NOV 2011) of 52.219-3.

[X] (12)(i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (OCT 2014) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

[] (ii) Alternate I (JAN 2011) of 52.219-4.

[] (13) [Reserved]

[] (14)(i) 52.219-6, Notice of Total Small Business Set-Aside (NOV 2011) (15 U.S.C. 644).

[] (ii) Alternate I (NOV 2011).

[] (iii) Alternate II (NOV 2011).

[] (15)(i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C. 644).

[] (ii) Alternate I (Oct 1995) of 52.219-7.

[] (iii) Alternate II (Mar 2004) of 52.219-7.

[X] (16) 52.219-8, Utilization of Small Business Concerns (OCT 2014) (15 U.S.C. 637(d)(2) and (3).

[] (17)(i) 52.219-9, Small Business Subcontracting Plan (OCT 2014) (15 U.S.C. 637(d)(4)).

[] (ii) Alternate I (Oct 2001) of 52.219-9.

[] (iii) Alternate II (Oct 2001) of 52.219-9.

[] (iv) Alternate III (OCT 2014) of 52.219-9.

[] (18) 52.219-13, Notice of Set-Aside of Orders (NOV 2011) (15 U.S.C. 644(r)).

[] (19) 52.219-14, Limitations on Subcontracting (NOV 2011) (15 U.S.C. 637(a)(14)).

[] (20) 52.219-16, Liquidated Damages—Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).

[] (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (NOV 2011) (15 U.S.C. 657f).

[X] (22) 52.219-28, Post Award Small Business Program Rerepresentation (Jul 2013) (15 U.S.C 632(a)(2)).

[] (23) 52.219-29, Notice of Set-Aside for Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (Jul 2013) (15 U.S.C. 637(m)).

[] (24) 52.219-30, Notice of Set-Aside for Women-Owned Small Business (WOSB) Concerns Eligible Under the WOSB Program (Jul 2013) (15 U.S.C. 637(m)).

[X] (25) 52.222-3, Convict Labor (June 2003) (E.O. 11755).

[X] (26) 52.222-19, Child Labor—Cooperation with Authorities and Remedies (JAN 2014) (E.O. 13126).

[X] (27) 52.222-21, Prohibition of Segregated Facilities (APR 2015).

[X] (28) 52.222-26, Equal Opportunity (APR 2015) (E.O. 11246).

[X] (29) 52.222-35, Equal Opportunity for Veterans (JUL 2014) (38 U.S.C. 4212).

[X] (30) 52.222-36, Equal Opportunity for Workers with Disabilities (JUL 2014) (29 U.S.C. 793).

[X] (31) 52.222-37, Employment Reports on Veterans (JUL 2014) (38 U.S.C. 4212).

[X] (32) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496).

[X] (33)(i) 52.222-50, Combating Trafficking in Persons (MAR 2015) (22 U.S.C. chapter 78 and E.O. 13627).

[] (ii) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

[] (34) 52.222-54, Employment Eligibility Verification (AUG 2013). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)

[] (35)(i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-Designated Items (May 2008) (42 U.S.C.6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

[] (ii) Alternate I (MAY 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

[] (36)(i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).

[] (ii) Alternate I (JUN 2014) of 52.223-13.

[] (37)(i) 52.223-14, Acquisition of EPEAT®-Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).

[] (ii) Alternate I (JUN 2014) of 52.223-14.

[] (38) 52.223-15, Energy Efficiency in Energy-Consuming Products (DEC 2007)(42 U.S.C. 8259b).

[] (39)(i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (JUN 2014) (E.O.s 13423 and 13514).

[] (ii) Alternate I (JUN 2014) of 52.223-16.

[X] (40) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (AUG 2011)

[X] (41) 52.225-1, Buy American—Supplies (MAY 2014) (41 U.S.C. chapter 83).

[] (42)(i) 52.225-3, Buy American—Free Trade Agreements—Israeli Trade Act (MAY 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

[] (ii) Alternate I (MAY 2014) of 52.225-3.

[] (iii) Alternate II (MAY 2014) of 52.225-3.

[] (iv) Alternate III (MAY 2014) of 52.225-3.

[X] (43) 52.225-5, Trade Agreements (NOV 2013) (19 U.S.C. 2501, *et seq.*, 19 U.S.C. 3301 note).

[X] (44) 52.225-13, Restrictions on Certain Foreign Purchases (JUN 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

[] (45) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Jul 2013) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

[] (46) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150).

[] (47) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).

[] (48) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

[] (49) 52.232-30, Installment Payments for Commercial Items (Oct 1995) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

[] (50) 52.232-33, Payment by Electronic Funds Transfer—System for Award Management (Jul 2013) (31 U.S.C. 3332).

[X] (51) 52.232-34, Payment by Electronic Funds Transfer—Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).

[] (52) 52.232-36, Payment by Third Party (MAY 2014) (31 U.S.C. 3332).

[] (53) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).

[] (54)(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).

[] (ii) Alternate I (Apr 2003) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[] (1) 52.222-17, Nondisplacement of Qualified Workers (MAY 2014) (E.O. 13495).

[] (2) 52.222-41, Service Contract Labor Standards (MAY 2014) (41 U.S.C. chapter 67).

[] (3) 52.222-42, Statement of Equivalent Rates for Federal Hires (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

[] (4) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards—Price Adjustment (Multiple Year and Option Contracts) (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

[] (5) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards—Price Adjustment (MAY 2014) (29 U.S.C 206 and 41 U.S.C. chapter 67).

[] (6) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment—Requirements (MAY 2014) (41 U.S.C. chapter 67).

[] (7) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services—Requirements (MAY 2014) (41 U.S.C. chapter 67).

[] (8) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2014) (Executive Order 13658).

[] (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (MAY 2014) (42 U.S.C. 1792).

[] (10) 52.237-11, Accepting and Dispensing of $1 Coin (SEP 2008) (31 U.S.C. 5112(p)(1)).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records—Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (APR 2010) (41 U.S.C. 3509).

(ii) 52.219-8, Utilization of Small Business Concerns (OCT 2014) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $650,000 ($1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(iii) 52.222-17, Nondisplacement of Qualified Workers (MAY 2014) (E.O. 13495). Flow down required in accordance with paragraph (l) of FAR clause 52.222-17.

(iv) 52.222-21, Prohibition of Segregated Facilities (APR 2015).

(v) 52.222-26, Equal Opportunity (APR 2015) (E.O. 11246).

(vi) 52.222-35, Equal Opportunity for Veterans (JUL 2014) (38 U.S.C. 4212).

(vii) 52.222-36, Equal Opportunity for Workers with Disabilities (JUL 2014) (29 U.S.C. 793).

(viii) 52.222-37, Employment Reports on Veterans (JUL 2014) (38 U.S.C. 4212).

(ix) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

(x) 52.222-41, Service Contract Labor Standards (MAY 2014) (41 U.S.C. chapter 67).

(xi)(A) 52.222-50, Combating Trafficking in Persons (MAR 2015) (22 U.S.C. chapter 78 and E.O. 13627).

(B) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

(xii) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment—Requirements (MAY 2014) (41 U.S.C. chapter 67).

(xiii) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services—Requirements (MAY 2014) (41 U.S.C. chapter 67).

(xiv) 52.222-54, Employment Eligibility Verification (AUG 2013).

(xv) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2014) (E.O. 13658).

(xvi) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Jul 2013) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(xvii) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (MAY 2014) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xviii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of Clause)

C.2 52.217-8 OPTION TO EXTEND SERVICES (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the delivery order. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days.

(End of Clause)

C.3 52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this delivery order by written notice to the Contractor within 30 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended delivery order shall be considered to include this option clause.

(c) The total duration of this delivery order, including the exercise of any options under this clause, shall not exceed five (5) years and (6) months..

(End of Clause)

C.4 VAAR 852.203-70 COMMERCIAL ADVERTISING (JAN 2008)

The bidder or offeror agrees that if a contract is awarded to him/her, as a result of this solicitation, he/she will not advertise the award of the contract in his/her commercial advertising in such a manner as to state or imply that the Department of Veterans Affairs endorses a product, project or commercial line of endeavor.

(End of Clause)

C.5 VAAR 852.203-71 DISPLAY OF DEPARTMENT OF VETERAN AFFAIRS HOTLINE POSTER (DEC 1992)

(a) Except as provided in paragraph (c) below, the Contractor shall display prominently, in common work areas within business segments performing work under VA contracts, Department of Veterans Affairs Hotline posters prepared by the VA Office of Inspector General.

(b) Department of Veterans Affairs Hotline posters may be obtained from the VA Office of Inspector General (53E), P.O. Box 34647, Washington, DC 20043-4647.

(c) The Contractor need not comply with paragraph (a) above if the Contractor has established a mechanism, such as a hotline, by which employees may report suspected instances of improper conduct, and instructions that encourage employees to make such reports.

(End of Clause)

C.6 52.216-18 – ORDERING

As prescribed in 16.506(a), insert the following clause:

Ordering (Oct 1995)

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from __31 August 2015____ through ___30 August 2020.

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of Clause)

C.7 52.216-19 – ORDER LIMITATIONS

As prescribed in 16.506(b), insert a clause substantially the same as follows:

Order Limitations (Oct 1995)

(a) *Minimum order*. When the Government requires supplies or services covered by this contract in an amount of less than ____$100.00_____ *[insert dollar figure or quantity]*, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) *Maximum order*. The Contractor is not obligated to honor --

(1) Any order for a single item in excess of ___$99,500.00_____;

(2) Any order for a combination of items in excess of __$99,500.00_____ or

(3) A series of orders from the same ordering office within _____1_____ days that together call for quantities exceeding the limitation in subparagraph (b)(1) or (2) of this section.

(c) If this is a requirements contract (*i.e.*, includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) of this section.

(d) Notwithstanding paragraphs (b) and (c) of this section, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within __1___ days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

(End of Clause)

C.8 52.216-22 – INDEFINITE QUANTITY

As prescribed in 16.506(e), insert the following clause:

Indefinite Quantity (Oct 1995)

(a) This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.

(b) Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."

(c) Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.

(d) Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after __30 August 2020__.

(End of Clause)

SECTION D - CONTRACT DOCUMENTS, EXHIBITS, OR ATTACHMENTS

EXHIBIT 1: 2015 Placebo Tablets

EXHIBIT 2: 2015 Coating Tablets

EXHIBIT 3: 2015 Active Capsule Filling

EXHIBIT 4: 2015 Capsule Filling on the Ultra 8II

EXHIBIT 5: 2015 Tablet Over encapsulation on Ultra 8II

EXHIBIT 6: 2015 Manufacturing Equipment

SECTION E - SOLICITATION PROVISIONS

E.1 52.212-2 EVALUATION—COMMERCIAL ITEMS (OCT 2014)

(a) The Government will award a contract resulting from this solicitation to the responsible offeror whose offer conforming to the solicitation will be most advantageous to the Government, price and other factors considered. The following factors shall be used to evaluate offers:

Lowest Price Technically Acceptable (LPTA) will be used to evaluate all RFQ Packages

Pass and Fail will be used to score each package

Award will be made to the technically acceptable offeror with the lowest evaluated price, which is deemed responsible in accordance with the Federal Acquisition Regulation and whose quote conforms to the requirements. Technical acceptability will be evaluated on a LPTA basis using Pass or Fail to score each package. Include prices for the entire project. Ensure technical requirements and specifications are met in accordance with (IAW) the Statement of Work (SOW) and/or Price Cost Schedule. Failure to meet any of the requirements may result in rejection of the entire offer. A partial quote will not be considered.

Technical Portion:. Ensure technical requirements and specification are met IAW with the SOW. Offerors will provide the following information for technical evaluation below 1-7.

FBR = Formulations and Batch Records

1. **The contractor shall confirm in writing that the individuals performing the work have experience providing formulations and batch records (FBRs) using the specific equipment owned by the CSPRPCC and for the processes covered under this contract. If the contractor has not worked with the specific equipment used by the CSPCRPCC the contractor must provide documentation of experience providing FBRs for equivalent equipment. The contractor must understand the basic requirements of the equipment and manufacturing processes as related to the equipment owned by the CSPCRPCC, the CSPCRPCC's processes and FBRs. This includes items such as defining the appropriate blender to use, blend times and the appropriate range for batch sizes to be manufactured, understanding the set-up process for capsule fillers and the appropriate pin sizes to use, etc.**

2. **The contractor shall provide documentation that they have worked with other organizations to include safety precautions for the FBRs to minimize or eliminate health and safety risk to the operators implementing the FBRs.**

3. **The contractor shall possess the knowledge to appropriately scale-up or scale down batch sizes.**

4. **The contractor shall have demonstrated experience working with low dose products using the types of equipment owned by the VACSPCRPCC, such as standard V-shell and/or ribbon blenders, tablet presses and capsule fillers.**

5. **The contractor will provide documentation of demonstrated experience showing they are successful at transferring FBRs from their facility to a manufacturing facility. This can include providing three references for the CSPCRPCC to call to confirm this experience.**

6. **The contractor must be available during normal working hours for the CSPCRPCC (7 a.m. – 4:30 p.m. Mountain Time) to answer questions regarding the FBRs provided and regarding problems encountered when using those documents. If possible, the contractor will be in a physical location with close proximity to the CSPRPCC to allow the contractor to look immediately look at blends and finished product produced and participate in meetings if problems are encountered with the FBRs.**

7. **The contractor shall provide documented evidence that the individuals performing the work have demonstrated experience developing active and placebo solid oral dosage form products (tablets and capsules) for clinical trials regulated by Food and Drug Administration (FDA), the European Union and other international regulatory agencies.**

8. **The contractor will provide at least three references for organizations for which the contractor has performed related work that the Contracting Officer or CSPCRPCC can call for information on their work.**

9. **The contractor will provide the CV for the lead individual expected to perform the work to assure they have the necessary education, training, background and experience to perform the work.**

10. **The contractor can document their ability to manufacture sample tablets and capsules.**

Technical and past performance, when combined, are less important compared to price.

(b) *Options.* The Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. The Government may determine that an offer is unacceptable if the option prices are significantly unbalanced. Evaluation of options shall not obligate the Government to exercise the option(s).

(c) A written notice of award or acceptance of an offer, mailed or otherwise furnished to the successful offeror within the time for acceptance specified in the offer, shall result in a binding contract without further action by either party. Before the offer's specified expiration time, the Government may accept an offer (or part of an offer), whether or not there are negotiations after its receipt, unless a written notice of withdrawal is received before award.

(End of Provision)

E.2 52.212-3 OFFEROR REPRESENTATIONS AND CERTIFICATIONS—COMMERCIAL ITEMS (MAR 2015)

The offeror shall complete only paragraph (b) of this provision if the offeror has completed the annual representations and certifications electronically via http://www.acquisition.gov. If an offeror has not completed the annual representations and certifications electronically at the System for Award Management (SAM) website, the offeror shall complete only paragraphs (c) through (p) of this provision.

(a) *Definitions.* As used in this provision—

"Economically disadvantaged women-owned small business (EDWOSB) concern" means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127. It automatically qualifies as a women-owned small business eligible under the WOSB Program.

"Forced or indentured child labor" means all work or service—

(1) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or

(2) Performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

"Highest-level owner" means the entity that owns or controls an immediate owner of the offeror, or that owns or controls one or more entities that control an immediate owner of the offeror. No entity owns or exercises control of the highest level owner.

"Immediate owner" means an entity, other than the offeror, that has direct control of the offeror. Indicators of control include, but are not limited to, one or more of the following: Ownership or interlocking management, identity of interests among family members, shared facilities and equipment, and the common use of employees.

"Inverted domestic corporation" means a foreign incorporated entity that meets the definition of an inverted domestic corporation under 6 U.S.C. 395(b), applied in accordance with the rules and definitions of 6 U.S.C. 395(c).

"Manufactured end product" means any end product in product and service codes (PSCs) 1000-9999, except—

(1) PSC 5510, Lumber and Related Basic Wood Materials;

(2) Product or Service Group (PSG) 87, Agricultural Supplies;

(3) PSG 88, Live Animals;

(4) PSG 89, Subsistence;

(5) PSC 9410, Crude Grades of Plant Materials;

(6) PSC 9430, Miscellaneous Crude Animal Products, Inedible;

(7) PSC 9440, Miscellaneous Crude Agricultural and Forestry Products;

(8) PSC 9610, Ores;

(9) PSC 9620, Minerals, Natural and Synthetic; and

(10) PSC 9630, Additive Metal Materials.

"Place of manufacture" means the place where an end product is assembled out of components, or otherwise made or processed from raw materials into the finished product that is to be provided to the Government. If a product is disassembled and reassembled, the place of reassembly is not the place of manufacture.

"Restricted business operations" means business operations in Sudan that include power production activities, mineral extraction activities, oil-related activities, or the production of military equipment, as those terms are defined in the Sudan Accountability and Divestment Act of 2007 (Pub. L. 110-174). Restricted business operations do not include business operations that the person (as that term is defined in Section 2 of the Sudan Accountability and Divestment Act of 2007) conducting the business can demonstrate—

(1) Are conducted under contract directly and exclusively with the regional government of southern Sudan;

(2) Are conducted pursuant to specific authorization from the Office of Foreign Assets Control in the Department of the Treasury, or are expressly exempted under Federal law from the requirement to be conducted under such authorization;

(3) Consist of providing goods or services to marginalized populations of Sudan;

(4) Consist of providing goods or services to an internationally recognized peacekeeping force or humanitarian organization;

(5) Consist of providing goods or services that are used only to promote health or education; or

(6) Have been voluntarily suspended.

"Sensitive technology"—

(1) Means hardware, software, telecommunications equipment, or any other technology that is to be used specifically—

(i) To restrict the free flow of unbiased information in Iran; or

(ii) To disrupt, monitor, or otherwise restrict speech of the people of Iran; and

(2) Does not include information or informational materials the export of which the President does not have the authority to regulate or prohibit pursuant to section 203(b)(3) of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)(3)).

"Service-disabled veteran-owned small business concern"—

(1) Means a small business concern—

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

"Small business concern" means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and size standards in this solicitation.

"Small disadvantaged business concern", consistent with 13 CFR 124.1002, means a small business concern under the size standard applicable to the acquisition, that—

(1) Is at least 51 percent unconditionally and directly owned (as defined at 13 CFR 124.105) by—

(i) One or more socially disadvantaged (as defined at 13 CFR 124.103) and economically disadvantaged (as defined at 13 CFR 124.104) individuals who are citizens of the United States; and

(ii) Each individual claiming economic disadvantage has a net worth not exceeding $750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(2) The management and daily business operations of which are controlled (as defined at 13.CFR 124.106) by individuals, who meet the criteria in paragraphs (1)(i) and (ii) of this definition.

"Subsidiary" means an entity in which more than 50 percent of the entity is owned—

(1) Directly by a parent corporation; or

(2) Through another subsidiary of a parent corporation.

"Veteran-owned small business concern" means a small business concern—

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

"Women-owned business concern" means a concern which is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women.

"Women-owned small business concern" means a small business concern—

(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

"Women-owned small business (WOSB) concern eligible under the WOSB Program" (in accordance with 13 CFR part 127), means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States.

(b)(1) *Annual Representations and Certifications.* Any changes provided by the offeror in paragraph (b)(2) of this provision do not automatically change the representations and certifications posted on the SAM website.

(2) The offeror has completed the annual representations and certifications electronically via the SAM website access through http://www.acquisition.gov. After reviewing the SAM database information, the offeror verifies by submission of this offer that the representations and certifications currently posted electronically at FAR 52.212-3, Offeror Representations and Certifications—Commercial Items, have been entered or updated in the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201), except for paragraphs .

(c) Offerors must complete the following representations when the resulting contract will be performed in the United States or its outlying areas. Check all that apply.

(1) *Small business concern*. The offeror represents as part of its offer that it [ ] is, [ ] is not a small business concern.

(2) *Veteran-owned small business concern.* [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.*] The offeror represents as part of its offer that it [ ] is, [ ] is not a veteran-owned small business concern.

(3) *Service-disabled veteran-owned small business concern.* [*Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (c)(2) of this provision.*] The offeror represents as part of its offer that it [ ] is, [ ] is not a service-disabled veteran-owned small business concern.

(4) *Small disadvantaged business concern.* [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.*] The offeror represents that it [ ] is, [ ] is not a small disadvantaged business concern as defined in 13 CFR 124.1002.

(5) *Women-owned small business concern.* [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.*] The offeror represents that it [ ] is, [ ] is not a women-owned small business concern.

(6) WOSB concern eligible under the WOSB Program. [Complete only if the offeror represented itself as a women-owned small business concern in paragraph (c)(5) of this provision.] The offeror represents that—

(i) It [ ] is, [ ] is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It [ ] is, [ ] is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(6)(i) of this provision is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. [*The offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture:* _____.] Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(7) Economically disadvantaged women-owned small business (EDWOSB) concern. [*Complete only if the offeror represented itself as a WOSB concern eligible under the WOSB Program in (c)(6) of this provision.*] The offeror represents that—

(i) It [ ] is, [ ] is not an EDWOSB concern, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It [ ] is, [ ] is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(7)(i) of this provision is accurate for each EDWOSB concern participating in the joint venture. [*The offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture:* _____.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

Note: Complete paragraphs (c)(8) and (c)(9) only if this solicitation is expected to exceed the simplified acquisition threshold.

(8) *Women-owned business concern (other than small business concern).* [*Complete only if the offeror is a women-owned business concern and did not represent itself as a small business concern in paragraph (c)(1) of this provision.*] The offeror represents that it [ ] is a women-owned business concern.

(9) *Tie bid priority for labor surplus area concerns.* If this is an invitation for bid, small business offerors may identify the labor surplus areas in which costs to be incurred on account of manufacturing or production (by offeror or first-tier subcontractors) amount to more than 50 percent of the contract price:

_____

(10) *HUBZone small business concern.* [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.*] The offeror represents, as part of its offer, that—

(i) It [ ] is, [ ] is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material change in ownership and control, principal office, or HUBZone employee percentage has occurred since it was certified by the Small Business Administration in accordance with 13 CFR Part 126; and

(ii) It [ ] is, [ ] is not a joint venture that complies with the requirements of 13 CFR Part 126, and the representation in paragraph (c)(10)(i) of this provision is accurate for the HUBZone small business concern or concerns that are participating in the joint venture. [The offeror shall enter the name or names of the HUBZone small business concern or concerns that are participating in the joint venture:_____.] Each HUBZone small business concern participating in the joint venture shall submit a separate signed copy of the HUBZone representation.

(d) Representations required to implement provisions of Executive Order 11246—

(1) *Previous contracts and compliance*. The offeror represents that—

(i) It [ ] has, [ ] has not participated in a previous contract or subcontract subject to the Equal Opportunity clause of this solicitation; and

(ii) It [ ] has, [ ] has not filed all required compliance reports.

(2) *Affirmative Action Compliance.* The offeror represents that—

(i) It [ ] has developed and has on file, [ ] has not developed and does not have on file, at each establishment, affirmative action programs required by rules and regulations of the Secretary of Labor (41 CFR parts 60-1 and 60-2), or

(ii) It [ ] has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(e) *Certification Regarding Payments to Influence Federal Transactions* (31 U.S.C. 1352). (Applies only if the contract is expected to exceed $150,000.) By submission of its offer, the offeror certifies to the best of its knowledge and belief that no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress or an employee of a Member of Congress on his or her behalf in connection with the award of any resultant contract. If any registrants under the Lobbying Disclosure Act of 1995 have made a lobbying contact on behalf of the offeror with respect to this contract, the offeror shall complete and submit, with its offer, OMB Standard Form LLL, Disclosure of Lobbying Activities, to provide the name of the registrants. The offeror need not report regularly employed officers or employees of the offeror to whom payments of reasonable compensation were made.

(f) *Buy American Certificate*. (Applies only if the clause at Federal Acquisition Regulation (FAR) 52.225-1, Buy American—Supplies, is included in this solicitation.)

(1) The offeror certifies that each end product, except those listed in paragraph (f)(2) of this provision, is a domestic end product and that for other than COTS items, the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The offeror shall list as foreign end products those end products manufactured in the United States that do not qualify

as domestic end products, i.e., an end product that is not a COTS item and does not meet the component test in paragraph (2) of the definition of "domestic end product." The terms "commercially available off-the-shelf (COTS) item," "component," "domestic end product," "end product," "foreign end product," and "United States" are defined in the clause of this solicitation entitled "Buy American—Supplies."

(2) Foreign End Products:

Line Item No	Country of Origin
_____	_____
_____	_____
_____	_____

[List as necessary]

(3) The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25.

(g)(1) *Buy American—Free Trade Agreements—Israeli Trade Act Certificate.* (Applies only if the clause at FAR 52.225-3, Buy American—Free Trade Agreements—Israeli Trade Act, is included in this solicitation.)

(i) The offeror certifies that each end product, except those listed in paragraph (g)(1)(ii) or (g)(1)(iii) of this provision, is a domestic end product and that for other than COTS items, the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The terms "Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end product," "commercially available off-the-shelf (COTS) item," "component," "domestic end product," "end product," "foreign end product," "Free Trade Agreement country," "Free Trade Agreement country end product," "Israeli end product," and "United States" are defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act."

(ii) The offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act":

Free Trade Agreement Country End Products (Other than Bahrainian, Moroccan, Omani, Panamanian, or Peruvian End Products) or Israeli End Products:

Line Item No.	Country of Origin
_____	_____
_____	_____
_____	_____

[List as necessary]

(iii) The offeror shall list those supplies that are foreign end products (other than those listed in paragraph (g)(1)(ii) of this provision) as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act." The offeror shall list as other foreign end products those end products manufactured in the United States that do not qualify as domestic end products, i.e., an end product that is not a COTS item and does not meet the component test in paragraph (2) of the definition of "domestic end product."

Other Foreign End Products:

Line Item No. Country of Origin

_____ _____

_____ _____

_____ _____

[List as necessary]

(iv) The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25.

(2) *Buy American—Free Trade Agreements—Israeli Trade Act Certificate, Alternate I.* If Alternate I to the clause at FAR 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Canadian end products as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act":

Canadian End Products:

Line Item No.

_____

_____

_____

[List as necessary]

(3) *Buy American—Free Trade Agreements—Israeli Trade Act Certificate, Alternate II.* If Alternate II to the clause at FAR 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Canadian end products or Israeli end products as defined in the clause of this solicitation entitled "Buy American—Free Trade Agreements—Israeli Trade Act":

Canadian or Israeli End Products:

Line Item No. Country of Origin

_____ _____

_____ _____

_____ _____

[List as necessary]

(4) *Buy American—Free Trade Agreements—Israeli Trade Act Certificate, Alternate III*. If Alternate III to the clause at FAR 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Free Trade Agreement country end products (other than Bahrainian, Korean, Moroccan, Omani, Panamanian, or Peruvian end products) or Israeli end products as defined in the clause of this solicitation entitled “Buy American—Free Trade Agreements—Israeli Trade Act”:

Free Trade Agreement Country End Products (Other than Bahrainian, Korean, Moroccan, Omani, Panamanian, or Peruvian End Products) or Israeli End Products:

Line Item No. Country of Origin

_____ _____

_____ _____

_____ _____

[List as necessary]

(5) *Trade Agreements Certificate.* (Applies only if the clause at FAR 52.225-5, Trade Agreements, is included in this solicitation.)

(i) The offeror certifies that each end product, except those listed in paragraph (g)(5)(ii) of this provision, is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled “Trade Agreements”.

(ii) The offeror shall list as other end products those end products that are not U.S.-made or designated country end products.

Other End Products:

Line Item No. Country of Origin

_____ _____

_____ _____

_____ _____

[List as necessary]

(iii) The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25. For line items covered by the WTO GPA, the Government will evaluate offers of U.S.-made or designated country end products without regard to the restrictions of the Buy American statute. The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation.

(h) *Certification Regarding Responsibility Matters* (Executive Order 12689). (Applies only if the contract value is expected to exceed the simplified acquisition threshold.) The offeror certifies, to the best of its knowledge and belief, that the offeror and/or any of its principals—

(1) [ ] Are, [ ] are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(2) [ ] Have, [ ] have not, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a Federal, state or local government contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or Commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property;

(3) [ ] Are, [ ] are not presently indicted for, or otherwise criminally or civilly charged by a Government entity with, commission of any of these offenses enumerated in paragraph (h)(2) of this clause; and

(4) [ ] Have, [ ] have not, within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds $3,000 for which the liability remains unsatisfied.

(i) Taxes are considered delinquent if both of the following criteria apply:

(A) *The tax liability is finally determined.* The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(B) *The taxpayer is delinquent in making payment.* A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(ii) *Examples.*

(A) The taxpayer has received a statutory notice of deficiency, under I.R.C. Sec. 6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(B) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. Sec. 6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the

underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(C) The taxpayer has entered into an installment agreement pursuant to I.R.C. Sec. 6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(D) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. 362 (the Bankruptcy Code).

(i) *Certification Regarding Knowledge of Child Labor for Listed End Products (Executive Order 13126).*

(1) *Listed end products.*

Listed End Product Listed Countries of Origin

(2) *Certification. [If the Contracting Officer has identified end products and countries of origin in paragraph (i)(1) of this provision, then the offeror must certify to either (i)(2)(i) or (i)(2)(ii) by checking the appropriate block.]*

[ ] (i) The offeror will not supply any end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product.

[ ] (ii) The offeror may supply an end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product. The offeror certifies that it has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any such end product furnished under this contract. On the basis of those efforts, the offeror certifies that it is not aware of any such use of child labor.

(j) *Place of manufacture.* (Does not apply unless the solicitation is predominantly for the acquisition of manufactured end products.) For statistical purposes only, the offeror shall indicate whether the place of manufacture of the end products it expects to provide in response to this solicitation is predominantly—

(1) __ In the United States (Check this box if the total anticipated price of offered end products manufactured in the United States exceeds the total anticipated price of offered end products manufactured outside the United States); or

(2) __ Outside the United States.

(k) *Certificates regarding exemptions from the application of the Service Contract Labor Standards.* (Certification by the offeror as to its compliance with respect to the contract also constitutes its certification as to compliance by its subcontractor if it subcontracts out the exempt services.)

[ ] (1) Maintenance, calibration, or repair of certain equipment as described in FAR 22.1003-4(c)(1). The offeror [ ] does [ ] does not certify that—

(i) The items of equipment to be serviced under this contract are used regularly for other than Governmental purposes and are sold or traded by the offeror (or subcontractor in the case of an exempt subcontract) in substantial quantities to the general public in the course of normal business operations;

(ii) The services will be furnished at prices which are, or are based on, established catalog or market prices (see FAR 22.1003- 4(c)(2)(ii)) for the maintenance, calibration, or repair of such equipment; and

(iii) The compensation (wage and fringe benefits) plan for all service employees performing work under the contract will be the same as that used for these employees and equivalent employees servicing the same equipment of commercial customers.

[ ] (2) Certain services as described in FAR 22.1003- 4(d)(1). The offeror [ ] does [ ] does not certify that—

(i) The services under the contract are offered and sold regularly to non-Governmental customers, and are provided by the offeror (or subcontractor in the case of an exempt subcontract) to the general public in substantial quantities in the course of normal business operations;

(ii) The contract services will be furnished at prices that are, or are based on, established catalog or market prices (see FAR 22.1003-4(d)(2)(iii));

(iii) Each service employee who will perform the services under the contract will spend only a small portion of his or her time (a monthly average of less than 20 percent of the available hours on an annualized basis, or less than 20 percent of available hours during the contract period if the contract period is less than a month) servicing the Government contract; and

(iv) The compensation (wage and fringe benefits) plan for all service employees performing work under the contract is the same as that used for these employees and equivalent employees servicing commercial customers.

(3) If paragraph (k)(1) or (k)(2) of this clause applies—

(i) If the offeror does not certify to the conditions in paragraph (k)(1) or (k)(2) and the Contracting Officer did not attach a Service Contract Labor Standards wage determination to the solicitation, the offeror shall notify the Contracting Officer as soon as possible; and

(ii) The Contracting Officer may not make an award to the offeror if the offeror fails to execute the certification in paragraph (k)(1) or (k)(2) of this clause or to contact the Contracting Officer as required in paragraph (k)(3)(i) of this clause.

(l) *Taxpayer Identification Number (TIN)* (26 U.S.C. 6109, 31 U.S.C. 7701). (Not applicable if the offeror is required to provide this information to the SAM database to be eligible for award.)

(1) All offerors must submit the information required in paragraphs (l)(3) through (l)(5) of this provision to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M, and implementing regulations issued by the Internal Revenue Service (IRS).

(2) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C. 7701(c)(3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror's TIN.

(3) *Taxpayer Identification Number (TIN).*

[ ] TIN: _____.

[ ] TIN has been applied for.

[ ] TIN is not required because:

[ ] Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;

[ ] Offeror is an agency or instrumentality of a foreign government;

[ ] Offeror is an agency or instrumentality of the Federal Government.

(4) *Type of organization.*

[ ] Sole proprietorship;

[ ] Partnership;

[ ] Corporate entity (not tax-exempt);

[ ] Corporate entity (tax-exempt);

[ ] Government entity (Federal, State, or local);

[ ] Foreign government;

[ ] International organization per 26 CFR 1.6049-4;

[ ] Other _____.

(5) *Common parent.*

[ ] Offeror is not owned or controlled by a common parent;

[ ] Name and TIN of common parent:

Name _____.

TIN _____.

(m) *Restricted business operations in Sudan.* By submission of its offer, the offeror certifies that the offeror does not conduct any restricted business operations in Sudan.

(n) *Prohibition on Contracting with Inverted Domestic Corporations*.

(1) Government agencies are not permitted to use appropriated (or otherwise made available) funds for contracts with either an inverted domestic corporation, or a subsidiary of an inverted domestic corporation, unless the exception at 9.108-2(b) applies or the requirement is waived in accordance with the procedures at 9.108-4.

(2) Representation. By submission of its offer, the offeror represents that—

(i) It is not an inverted domestic corporation; and

(ii) It is not a subsidiary of an inverted domestic corporation.

(o) *Prohibition on contracting with entities engaging in certain activities or transactions relating to Iran.*

(1) The offeror shall email questions concerning sensitive technology to the Department of State at CISADA106@state.gov.

(2) *Representation and certifications.* Unless a waiver is granted or an exception applies as provided in paragraph (o)(3) of this provision, by submission of its offer, the offeror—

(i) Represents, to the best of its knowledge and belief, that the offeror does not export any sensitive technology to the government of Iran or any entities or individuals owned or controlled by, or acting on behalf or at the direction of, the government of Iran;

(ii) Certifies that the offeror, or any person owned or controlled by the offeror, does not engage in any activities for which sanctions may be imposed under section 5 of the Iran Sanctions Act; and

(iii) Certifies that the offeror, and any person owned or controlled by the offeror, does not knowingly engage in any transaction that exceeds $3,000 with Iran's Revolutionary Guard Corps or any of its officials, agents, or affiliates, the property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (see OFAC's Specially Designated Nationals and Blocked Persons List at *http://www.treasury.gov/ofac/downloads/t11sdn.pdf*).

(3) The representation and certification requirements of paragraph (o)(2) of this provision do not apply if—

(i) This solicitation includes a trade agreements certification (*e.g.*, 52.212–3(g) or a comparable agency provision); and

(ii) The offeror has certified that all the offered products to be supplied are designated country end products.

(p) *Ownership or Control of Offeror.* (Applies in all solicitations when there is a requirement to be registered in SAM or a requirement to have a DUNS Number in the solicitation.)

(1) The Offeror represents that it [ ] has or [ ] does not have an immediate owner. If the Offeror has more than one immediate owner (such as a joint venture), then the Offeror shall respond to paragraph (2) and if applicable, paragraph (3) of this provision for each participant in the joint venture.

(2) If the Offeror indicates "has" in paragraph (p)(1) of this provision, enter the following information:

Immediate owner CAGE code:

_____

Immediate owner legal name:

_____

(*Do not use a "doing business as" name*)

Is the immediate owner owned or controlled by another entity: [ ] Yes or [ ] No.

(3) If the Offeror indicates "yes" in paragraph (p)(2) of this provision, indicating that the immediate owner is owned or controlled by another entity, then enter the following information:

Highest-level owner CAGE code:

_____

Highest-level owner legal name:

_____

(*Do not use a "doing business as" name*)

(End of Provision)