

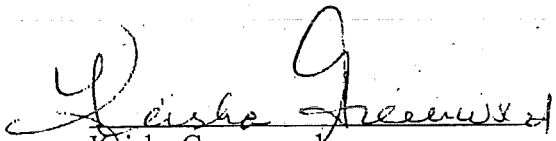
DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: VA69D-17-AP-2059

1. **Contracting Activity:** Department of Veterans Affairs, VISN 12, Hines Medical Center, and Pharmacy Benefits Management. NCO 12, Great Lakes Acquisition Center (GLAC). 2237, 578-17-1-715-0018.
2. **Nature and/or Description of the Action Being Processed:** Justification and approval for a Contact to provide the drug Relenza for a total of \$3,904,776.00 in accordance with FAR 13.5, Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Relenza (NDC# 00173-0681-22) is an oral inhalation which is FDA approved for treatment and prophylaxis of influenza A and B virus. Although there are other drugs with similar indications, this is the only oral inhalation product, and it is important to have this agent as part of the VA All-Hazards Emergency Cache (VHA Directive 1047(1)) as a treatment option for patients that cannot swallow a pill or tablet and may need treatment or prophylaxis in a pandemic influenza event. This is a branded pharmaceutical product, and to date, there are no generic equivalents available.
4. **Statutory Authority Permitting Other than Full and Open Competition:**
The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**
The National Drug Code (NDC) that is being requested in the solicitation is a government specific product for stock piling in the event of a national emergency. Though this drug is offered on NAC FSS, those contract terms allow for expired drugs to be returned. The manufacturer, Glaxo Smith Kline, created this number for the purposes of supplying emergency stock piles, which are non-returnable. This particular NDC is only available directly from the manufacturer, as the manufacturer can more easily control the lot numbers and expiration date. The government can be provided with product directly from the manufacturing line, which assures the longest expiration dating for the product being stockpiled. This, in turn, minimizes the waste that would be associated with frequently rotating short dated stock in emergency drug caches.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: As stated above this drug is only available from the manufacturer GSK.
7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable: Commercially this drug is listed at \$57.52 per unit on FSS. Due to the special non-returnable requirement and quantity needed for the VA All-Hazard Emergency Cache program, GSK is offering the government a price of \$17.47 per unit. That is a savings of \$9,025,720.
8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted: The only market research conducted was to review the NDC code and confirm that it was not commercially available. Though the drug name Relenza was listed on FSS, this special pricing is for non-returnable product and only available open market for the VA All-Hazard Emergency Cache program.
9. Any Other Facts Supporting the Use of Other than Full and Open Competition: This particular NDC is only available directly from the manufacturer, as the manufacturer can more easily control the lot numbers and expiration date of the product that is sold to the government for stockpile purposes.
10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: Intent to sole source was posted to FBO and no responses were received.
11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required: None.
12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.


Keisha Greenwood
Administrative Officer
Pharmacy Benefits Management/Hines

2/1/2017
Date

13. Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.

- a. Contracting Officer or Designee's Certification (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Teresa J Beers-
WESOLOWSKI 324002

Teresa Beers-Wesolowski
Contracting Officer
GLAC

Digitally signed by Teresa J Beers-WESOLOWSKI 324002
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0.9.2342.19200300.100.1.1=teresa.beers-wesolowski@va.gov,
cn=Teresa J Beers-WESOLOWSKI 324002
Date: 2017.02.01 08:13:29 -06'00'

Date

- b. **Director of Contracting /Designee (Required over\$150K but not exceeding \$700K):**
I certify the justification meets requirements for other than full and open competition.

Diane M Brazale 348123

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0.9.2342.19200300.100.1.1=diane.brazale@va.gov, cn=Diane M
Brazale 348123
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Diane Brazale
NCO 12 Director of Contracting or Designee
GLAC

Date

- c. **VHA SAO HCA Review and Approval:** I have reviewed the foregoing justification
and find it to be complete and accurate to the best of my knowledge and belief and
recommend approval (if over \$13.5 million) or approve (\$700K to 13.5 million) for
other than full and open competition.

Linda S.
Greaves 404790

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a.gov, cn=Linda S. Greaves 404790
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Linda S. Greaves
Acting Director, SAO Central Region
SAO Central Head of Contracting Activity (HCA)

2/7/2017

Date