

**Department of Veterans Affairs  
Office of Acquisition and Logistics  
National Acquisition Center, National Contract Service  
Hines, Illinois 60141**

**Justification for Other than Full and Open Competition**

**(1) Identification of Agency and Contracting Activity and specific identification of the document:**

Justification for other than full and open competition is provided by The Department of Veterans Affairs, Office of Acquisition and Logistics, National Acquisition Center. This document sets forth the justification and approval for other than full and open competition for the acquisition described herein, under the authority of FAR 6.302-1 "only one responsible source and no other supplies or services will satisfy agency requirements".

**(2) Nature and/or description of the action being provided:**

The Government intends to enter into a sole source contract with Sanofi Pasteur, Inc. for Fluzone ® High-Dose Influenza Virus Vaccine designed specifically for persons 65 years of age and older for the 2014-2015 influenza season for which will include requirements for VA, BOP, and IHS facilities. The contemplated contract will have a 12 month period. Fluzone ® High-Dose Influenza Virus Vaccine was provided by Sanofi to VA and other government agencies through national contract VA797P-13-C-0044 for the 2013-2014 influenza season which was awarded and administered by the National Acquisition Center.

**(3) Description of the supplies or services required to meet the agency's needs (including the estimated value)**

Each year, the Veterans Health Administration (VHA) Pharmacy Benefits Management (PBM) identifies the procurement of influenza vaccine, in both multi-dose vials and single-dose pre-filled syringes, as critical to the agency's mission to meet the Advisory Committee on Immunization Practices' recommendations presented by the Center for Disease Control (CDC). This flu season VHA indicated that a need exists for Fluzone ® High-Dose Influenza Virus Vaccine designed specifically for persons 65 years of age and older, based on the attached clinical justification.

The contractor shall be required to provide the estimated requirements of 316,680 doses of Fluzone ® High-Dose Influenza Virus Vaccine to meet the agencies' (VA, IHS, BOP) needs.

The estimated value of this line item is \$6,710,885 for the 12 month period.

**(4) Identification of the statutory authority permitting other than full and open competition:**

The statutory authority permitting other than full and open competition is 41 U.S.C. 253 (c) (1) as implemented by FAR 6.302-1, which authorizes, under certain conditions, contracting without providing for full and open competition when the agencies' requirements can only be provided from one responsible source and no other supplies or services will satisfy agency requirements.

**(5) Demonstration that the proposed contractor's unique qualifications or the nature of the acquisition requires use of the authority cited:**

All influenza vaccines are considered a new branded drug every year, subject to Public Law 102-585, and are unique to each manufacturer. Sanofi Pasteur is currently the only manufacturer of high-dose influenza virus vaccine for the age indication of 65 years and older. VHA indicates that a need exists for this type of vaccine based on the attached Clinical Justification. No other source can meet the government's needs for the high-dose influenza virus vaccine over the contemplated contract period (12 months) because Sanofi Pasteur currently holds a patent, and thus market exclusivity.

**(6) Description of the efforts made to ensure that offers are solicited from as many potential sources as is practicable, including whether a notice was or will be publicized as required by Subpart 5.2 and , if not, which exception under 5.202 applies:**

For the reasons stated above Sanofi Pasteur is the only potential source of high-dose influenza virus vaccine. A pre-solicitation notice will be publicized on the Federal Business Opportunities website at [www.fbo.gov](http://www.fbo.gov) with the Government's intent to sole source this vaccine. Justification & Approval will be synopsized within with the solicitation.

**(7) A determination by the contracting officer that the anticipated cost to the Government will be fair and reasonable:**

A determination of fair and reasonable price will be made prior to award based on the analysis of current commercial market prices. In addition, the Federal Ceiling Price (FCP) will apply to each drug in accordance with Public Law 102-585 and the Government will not pay more than the calculated FCP for influenza vaccine.

**(8) A description of the market research conducted, the results or a statement of the reason market research was not conducted.**

Market Research concluded that there is only one known manufacturer of Fluzone ® High-Dose influenza virus vaccine that will meet the Government's requirement for the age indication of 65 years and older, based on the list of approved influenza virus vaccines published by the Center for Disease Control (CDC).

**(9) Other facts supporting the use of other than full and open competition:**

See attached clinical justification.

(10) **List of sources, if any, that expressed, in writing, an interest in the acquisition:**

In accordance with FAR 6.302-1(c)(1)(ii)(c) & 6.305(c) this justification will be posted with the government's solicitation. However, for the reasons stated above, there is no expectation that any other source will be able to participate in this procurement.

(11) **Statement of actions the agency may take to remove or overcome any barriers to competition before any subsequent acquisition for the supplies or services required:**

Sanofi Pasteur is currently the sole manufacturer of the branded drug Fluzone ® High-Dose Influenza Virus Vaccine that will meet the Government's requirement for the age indication of 65 years and older for the 2014-2015 influenza vaccine season. Market research will be conducted next flu season to ascertain if competition is available for an influenza vaccine for this age indication.

**TECHNICAL AND REQUIREMENTS CERTIFICATION**

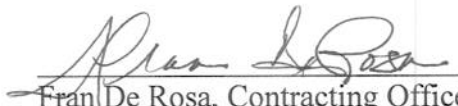
I certify that the facts and representations under my cognizance which are included in this justification and which form a basis for this justification are complete and accurate.

  
\_\_\_\_\_  
VHA Pharmacy Benefits Management

2/24/14  
\_\_\_\_\_  
Date

**CONTRACTING OFFICER CERTIFICATION**

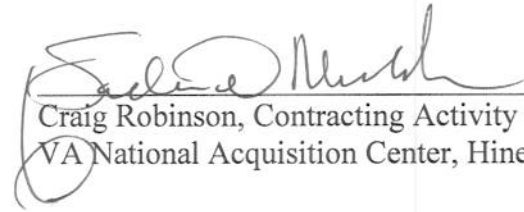
I certify that this justification is accurate and complete to the best of my knowledge and belief.

  
\_\_\_\_\_  
Fran De Rosa, Contracting Officer  
VA National Acquisition Center, Hines, Illinois

2/25/14  
\_\_\_\_\_  
Date

**CONTRACTING ACTIVITY COMPETITION ADVOCATE  
REVIEW AND APPROVAL**

Approval of this action is granted based on the above Justification and Certifications from Pharmacy Benefits Management and the Contracting Officer.

  
\_\_\_\_\_  
Craig Robinson, Contracting Activity Competition Advocate  
VA National Acquisition Center, Hines, Illinois

2/25/14  
\_\_\_\_\_  
Date

### Fluzone High-Dose Sole Source Clinical Justification

Individuals 65 years old and greater make up 90% of the deaths associated with influenza each year. It has been estimated that over 225,000 persons are hospitalized and 36,000 die due to influenza and resultant complications annually in the US. Vaccination against influenza is the single best way to decrease morbidity and mortality due to influenza infection.

While influenza vaccine has been shown to be highly effective in young, otherwise healthy persons, influenza vaccine is less effective in older persons. At least one reason for this difference is that influenza vaccine is less immunogenic in persons at the extremes of age and in those with underlying health conditions<sup>1</sup>. Since the 1970s research has been performed to determine ways to make the influenza vaccine more immunogenic. One simple solution has been to increase the amount of influenza virus antigen in the vaccine

Reasonable evidence exists to suggest that high dose vaccine will provide protection superior to standard dose. Use may prevent some hospitalizations and deaths.

Fluzone High-Dose is the only high-dose seasonal influenza vaccine commercially available in the United States and is a sole source product of Sanofi Pasteur. Healthcare professionals must have every tool accessible to prevent avoidable influenza infections in the elderly, and Fluzone High-Dose is a vital component of that strategy.

Signature Vincent Calabrese

Date 1/13/2014

Vincent Calabrese, Pharm.D.  
Associate Chief Consultant  
Pharmacy Benefits Management Services

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<sup>1</sup> Goodwin K, et al. *Vaccine* 2006;24:1159-69..