

**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® Quadrivalent 0.25 mL single-dose prefilled syringe. This influenza virus vaccine is designed specifically for children 6–35 months for the 2015-2016 influenza season for which will include requirements for IHS facilities. The contemplated contract will have a 12 month period. Fluzone ® Quadrivalent 0.25 mL single-dose prefilled syringe was provided by Sanofi to VA and other government agencies through national contract VA797P-14-C-0007 for the 2014-2015 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 IHS indicated that a need exists for Fluzone ® Quadrivalent 0.25 mL single-dose prefilled syringe 6–35 months.

The contractor shall be required to provide the estimated requirements of 4,890 doses of Fluzone ® Quadrivalent 0.25 mL single-dose prefilled syringe 6–35 months to meet IHS needs.

The estimated value of this line item is \$78,118 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 Fluzone ® Quadrivalent 0.25 mL single-dose prefilled syringe for children 6–35 months. IHS indicates that a need exists to vaccinate children between the ages of 6 months and 36 months old. No other source can meet the government's needs for influenza virus vaccine 0.25 mL single-dose prefilled syringe for children between 6–35 months old over the contemplated contract period (12 months).

(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 Quadrivalent 0.25 mL single-dose prefilled syringe influenza high-dose influenza virus vaccine. A pre-solicitation notice will be publicized on the Federal Business Opportunities website at www.fbo.gov with the Government's intent to sole source this vaccine. Justification & Approval will be synopsized within 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 ® Trivalent or Quadrivalent 0.25 mL single-dose prefilled syringe for children 6–35 months influenza virus vaccine that will meet the Government's requirement for the age indication of 6 month to 35 months approved influenza virus vaccines published by the Center for Disease Control (CDC) attached.

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

None

- (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® Quadrivalent 0.25 mL single-dose prefilled syringe influenza Influenza Virus Vaccine that will meet the Government's requirement for the age indication of 3 months to 35 months old 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.

For Rob Itayes Matt Bala
Indian Health Services – Pharmacy
Acting Director NSSC

2-25-14
Date

CONTRACTING OFFICER CERTIFICATION

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

Erika Moreno, Contracting Officer
VA National Acquisition Center, Hines, Illinois

2/25/2015
Date