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Comptroller General
of the United States

United States Government Accountability Office
Washington, DC 20548

Decision

Matter of: Protein Sciences Corporation

File: B-412794

Date: June 2, 2016

Wayne Hachey, for the protester.
Robert Bailey, Jr., Esq., and Jared P. Weissberger, Esq., Defense Logistics Agency, for the agency.
Young H. Cho, Esq., and Christina Sklarew, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

Protest challenging solicitation requirements for pre-filled syringes as unduly restrictive is denied where the record supports the agency's position that the requirement is reasonably necessary to meet the agency's needs.

DECISION

Protein Sciences Corporation (PSC) of Meriden, Connecticut, challenges the terms of request for proposal (RFP) No. SPE2DP-16-R-0004, issued by the Defense Logistics Agency (DLA) for influenza virus vaccines. PSC argues that the agency's requirement for pre-filled syringes is unduly restrictive of competition.

We deny the protest.

BACKGROUND

The RFP, issued on February 17, 2016, under Federal Acquisition Regulation (FAR) part 12, contemplated the award of a single, fixed-price, indefinite-quantity contract. RFP at 1, 32.[1] The solicitation contained seven contract line item numbers (CLINs) seeking an estimated total of 2,600,000 doses of a trivalent or quadrivalent influenza virus vaccine in multi-dose vials and single-dose pre-filled syringes. Id.

[1] The solicitation was amended two times. All citations to the RFP are to the final version, as amended.

at 4-7. At issue here is CLIN 0002, which seeks approximately 62,000 packages of 10 (i.e., a total of 620,000 doses) pre-filled syringes of the influenza virus vaccine for ages 18 years or older.[2] Id. at 4. As relevant here, the solicitation specified that each single-dose presentation "shall include one dose suitable for . . . adults . . . . The vaccine presented in single dose presentations shall be free of thimerosal or other preservatives." Id. at 8.

Prior to the solicitation closing date, the protester inquired as to whether "preservative free single dose vial presentations" would be considered equivalent to the single-dose syringes required under CLIN 0002. Agency Report (AR), Tab 4, February 17, 2016 email from PSC to Contracting Officer. The agency responded that "[t]he solicitation calls for pre-filled syringes and the [single-dose] vials are unacceptable to our customer." AR, Tab 5, February 24, 2016 email from Contracting Officer to PSC. This protest follows.

DISCUSSION

The protester argues that the agency's requirement for pre-filled syringes is unduly restrictive of competition and that the agency should include single-dose vials in CLIN 0002. Protest at 1. In this regard, the protester contends that the "primary rationale for using a single-dose preparation is to provide a preservative free product," and argues that the single-dose vial that PSC offers meets this requirement. Id.

Where a protester challenges a specification or requirement as unduly restrictive of competition, the procuring agency has the responsibility of establishing that the specification or requirement is reasonably necessary to meet the agency's needs. See Streit USA Armoring, LLC, B-408584, Nov. 5, 2013, 2013 CPD ¶ 257 at 4. We examine the adequacy of the agency's justification for a restrictive solicitation provision to ensure that it is rational and can withstand logical scrutiny. SMARTnet, Inc., B-400651.2, Jan. 27, 2009, 2009 CPD ¶ 34 at 7. A protester's disagreement with the agency's judgment concerning the agency's needs and how to accommodate them does not show that the agency's judgment is unreasonable. Exec Plaza, LLC, B-400107, B-400107.2, Aug. 1, 2008, 2008 CPD ¶ 143 at 5.

The agency responds that the protester's assumption that the purpose of the pre-filled syringes is to ensure that they are preservative free is incorrect. AR, Combined Contracting Officer Statement of Facts and Memorandum of Law (COSF/MOL) at 3. The agency states that for single-dose presentations, pre-filled

[2] While not challenged here, CLINs 0004 (440,000 doses), 0006 (700,000 doses), and 0007 (180,000 doses) also required pre-filled syringes for ages 9 and older, 36 months and older, and 6 months to 36 months. See RFP at 5-7. The remaining CLINs required multi-dose vials. Id. at 4-5.

syringes are a minimum requirement and that single-dose vials do not satisfy the government's requirements as stated in the solicitation. Id. at 1. In support of this contention, the agency provides a declaration from the Chief of the Public Health Division for the Defense Health Agency who is responsible for representing the Department of Defense on immunization matters and coordinating such requirements with the military services. See AR, Tab 2, Declaration of C. Fisher, Col, USAF, BSC. The agency explains that the requirement for pre-filled syringes, instead of single-dose vials, is based on the time savings these provide, which is necessary for large-scale immunizations to be administered in a safe, effective, and efficient manner. AR, COSF/MOL at 3; AR, Tab 2, Declaration of C. Fisher at 1. In this regard, the agency explains that immunizations using single-dose vials require additional steps to administer, which effectively doubles the vaccine administration time and negatively impacts the government's ability to administer its annual influenza vaccination program. AR, COSF/MOL at 3; AR, Tab 2, Declaration of C. Fisher at 1.

The agency also explains that single-dose vials have not been used in the past for large-scale inoculation campaigns and therefore would require the government to develop and conduct additional training for the large number of personnel involved in administering the flu vaccine. AR, COSF/MOL at 3-4; AR, Tab 2, Declaration of C. Fisher at 1. Additionally, the agency states that because the use of single-dose vials requires a separate syringe and additional alcohol swab for each vial, it would increase costs and also require additional physical space for storage. AR, COSF/MOL at 3; AR, Tab 2, Declaration of C. Fisher at 1. Finally, the agency states that use of pre-filled syringes has been associated with a decreased risk of needle-stick injury, when compared with use of vaccine vials. AR, COSF/MOL at 4; AR, Tab 2, Declaration of C. Fisher at 2.

We find that the agency has established that the requirement for pre-filled syringes is reasonable. Although the protester raises a number of arguments disagreeing with the agency, this disagreement does not show that the agency's judgment as to the need for pre-filled syringes is unreasonable. For example, the protester reiterates its position that the government's need for single-dose syringes was only due to the need for preservative free influenza vaccines. Comments at 1. In this regard, the protester claims that the "Department of Defense Guidance Regarding Thimerosal Containing Vaccines," which defines the preservative free requirement, does not reference a single-dose syringe requirement. Id.; see also Comments, attach. 1, Department of Defense Guidance Regarding Thimerosal Containing Vaccines. Observing that prior to the Food and Drug Administration's approval of PSC's product, all preservative free vaccines were in the form of single-dose syringes, PSC argues that the agency's failure to include a single-dose vial option or a specific line item for its product reflects a loss of perspective of the initial intent of the policy and "a lack of due diligence in examining all acceptable presentations." Comments at 1.

Similarly, the protester claims that to the extent the agency had concerns about needle-stick injuries, time for administration, and storage of ancillary supplies, "the bulk of the DLA order should reflect a single dose presentation rather than the multidose vials that represent the overwhelming majority of the DLA solicitation." Id. In fact, the majority of the agency's requirements are for single-dose pre-filled syringes; multi-dose vials represent approximately one-quarter of the agency's requirements. See RFP at 4-6. The protester also challenges the agency's assertion that the use of single-dose vials would necessitate additional training. Comments at 2. The protester argues that this is "at best a gross overstatement" because guidance on how to administer each year's influenza portfolio, published each year, "already includes instruction for injectable vaccine." Id. However, the referenced guidance simply provides, with regard to vaccine administration, "Administer 0.5 mL injectable inactivated vaccine (IIV) intramuscularly in the deltoid muscle. Use a 22-25g, 1-1 ½" needle. Always shake the syringe and multi-dose vial before withdrawing and administering every dose of vaccine." See Comments, attach. 3, Standing Order for the Administration of the Influenza Vaccine to Adults 2015-2016 at 2. PSC's contentions in this regard do not demonstrate that the agency's basis for these requirements was unreasonable.

A protester's disagreement with the agency's judgment concerning the agency's needs and how to accommodate them, without more, does not show that the agency's judgment is unreasonable. Exec Plaza, LLC, supra, at 5-6. Rather, we find that DLA's explanation for this restrictive solicitation provision withstands logical scrutiny and is rational.

The protest is denied.

Susan A. Poling
General Counsel