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Comptroller General
of the United States

United States Government Accountability Office
Washington, DC 20548

Decision

Matter of: Panacea Biotec, Inc.

File: B-400776

Date: January 21, 2009

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DIGEST

Agency reasonably excluded the protester's proposal from the competitive range, where the agency reasonably determined that the protester's proposal contained major and significant weaknesses and deficiencies, such that the proposal was found to be unacceptable, would require major revisions to be made acceptable, and was significantly lower rated than the proposals included in the competitive range.

DECISION

Panacea Biotec, Inc. of Boyds, Maryland,[1] protests the exclusion of its proposal from the competitive range under request for proposals (RFP) No. RFP-BARDA-08-15, issued by the Department of Health and Human Services (HHS), Biomedical Advanced Research and Development Authority, for 25 million doses of recombinant protective antigen (rPA) anthrax vaccine.

We deny the protest.

Following the deliberate exposure of individuals in the United States to bacillus anthracis (anthrax) in 2001, the federal government decided to procure and stockpile safe and efficient anthrax vaccines. RFP at 3. The RFP was issued in support of this decision, seeking offers to provide personnel, facilities, material, equipment and

[1] Panacea Biotec, Inc., which is incorporated in Delaware, is a subsidiary of Panacea Biotec, Ltd., which is headquartered in New Delhi, India. Protest at 2; Agency Report (AR), Tab 6, Panacea Proposal Transmittal Letter to HHS, July 24, 2008, at 1.

services to produce, test, formulate, fill, package, store, and deliver the rPA anthrax vaccine.

The RFP provided for the award of multiple contracts, with both fixed-price and cost-plus-fixed-price line items, for the delivery of 25 million doses of the vaccine within a 5 year anticipated period of performance, and with the possibility of three additional 1-year no-cost extensions. RFP, Statement of Objectives (SOO), at 8. The SOO identified contract objectives and requirements in a number of areas, including manufacturing; assay validation; clinical and non-clinical studies; shipment, storage and disposition; business management; program management; and risk mitigation. See id. at 8-12; see also RFP amend. 4, at 3-5. Offerors were informed that

> [a]cceptance of the rPA anthrax vaccine into the Strategic National Stockpile (SNS) [would] be contingent upon the Contractor providing sufficient safety, immunogenicity, efficacy, stability, manufacturing and any other data and information, as determined by the Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) for potential use of the product in a post-exposure prophylaxis (PEP) scenario in a declared emergency under an Emergency Use Authorization (EUA)

and that

> the Contractor will seek licensure for pre-exposure prophylaxis (also referred to as general use prophylaxis or GUP) in adults.

RFP at 3.[2] In this regard, offerors were required to "submit an Integrated Master Project Plan (including tabular and Gantt forms) that clearly indicate[d] the critical path to support an EUA and licensure." RFP amend. 4, at 3.

The solicitation also identified, as a "mandatory criterion for eligibility," the requirement that offerors provide a "dedicated section in the technical proposal" that shows that

> the Offeror has obtained FDA/CBER 'current thinking' for an rPA anthrax vaccine that describes the minimum product information and data that must be submitted to the FDA for review in order to potentially consider use of the product in a declared emergency under EUA.

RFP at 48.

[2] The RFP referred offerors to an FDA website for information concerning EUA. RFP, SOO, at 8.

Additional proposal preparation instructions were detailed in section L of the solicitation. Among other things, offerors were required to demonstrate their understanding of, and approach to fulfilling, the SOO. RFP 39, 43.

The RFP provided for award on a "best value" basis and identified the following four evaluation factors: technical proposal evaluation, past performance, small disadvantaged business participation, and cost/price. The non-cost/price evaluation factors were identified as being in descending order of importance and were stated to be, when combined, approximately equal in weight to the cost/ price factor. RFP at 48, 57. With regard to the technical proposal evaluation factor, the RFP stated that "proposals will be evaluated with points assigned as indicated in the following 6 categories [subfactors]" (for 320 total possible points): technical merit of offeror's proposal and time line (30 points), technical approach for manufacturing 25 million doses of rPA anthrax vaccine and obtaining licensure (180 points), personnel (30 points), facilities and equipment (25 points), project management and risk mitigation (20 points), and security (15 points).[3] RFP at 48-50.

Additional information was provided for each technical proposal evaluation subfactor, which, among other things, described the basis upon which points would be assigned. For example, under the technical approach subfactor (for which proposals could receive a maximum of 180 points), offerors were informed, among other things, that a maximum of 30 points would be assigned where "[c]ontractor has demonstrated validated bulk drug substance (BDS) production at proposed commercial scale." RFP at 49. Similarly, under the personnel subfactor, offerors were informed that HHS would evaluate whether an offeror had provided personnel who possess "the necessary education, training, and experience to successfully perform the work identified in the technical proposal." Id.

HHS received proposals from four offerors, including Panacea, which were evaluated by the agency's technical evaluation panel (TEP). Panacea, which had previously produced a recombinant anthrax vaccine in India, offered a vaccine based upon a modified clone, because its earlier produced vaccine was based upon a clone that Panacea believed would have to be modified "to comply with United States regulatory requirements." AR, Tab 6, Panacea Technical Proposal, at 4; Protest at 2.

Evaluation forms were completed for each offeror's proposal that described, in a narrative form, major strengths, significant strengths, minor strengths, major weaknesses, significant weaknesses, minor weaknesses, and deficiencies assessed under the technical proposal evaluation factor and its subfactors. Evaluators also assigned point scores for each technical proposal evaluation subfactor, and provided

[3] The RFP also provided 20 possible points for options evaluation.

an overall evaluation of whether the proposal was technically "acceptable" or "unacceptable." An unacceptable proposal was defined as follows:

> the proposal contains deficiencies that are so substantive as to preclude any possibility of it being upgraded to a level that meets the minimum requirements of the RFP, except though major revisions and additions that would be tantamount to the submission of a new proposal.

An acceptable proposal was defined to be a proposal that contains no deficiencies or "contains one or more deficiencies that the Offeror is likely to easily address by quickly providing additional information." See, e.g., AR, Tab 10, Individual Technical Evaluation Score Sheets for Panacea, Inc., at 10.

Panacea's and the two highest-rated offerors' initial proposals were evaluated under the technical proposal evaluation factor and subfactors as follows:[4]

	Panacea	**Offeror A**	**Offeror B**
Technical Merit/Timeline	16	21	21
Technical Approach	76	120	128
Personnel	13	26	14
Facilities/Equipment	19	20	19
Project Management & Risk Mitigation	6	16	15
Security	8	14	14
Option 1 for Label Extension for Expiry Period	5	8	8
Option 2 for Label Indication Extension for Pediatric & Geriatric Populations	7	7	8
TOTAL (of 320 points)	**150**	**232**	**228**
Acceptable/Unacceptable	U	A	A

AR, Tab 12, TEP Evaluation Report, at 3. The TEP also found that the proposals of these three offerors satisfied the solicitation's mandatory requirement that offerors obtain FDA's "current thinking" for an rPA anthrax vaccine.

[4] The proposal of the lowest-rated offeror, whose evaluation results under the technical proposal evaluation factor is not shown here, received only 60 total points under this factor and its proposal was excluded from the competitive range.

Panacea's unacceptable rating reflected the TEP's judgment that, although Panacea (as an established vaccine manufacturer and supplier) had offered a number of proposal strengths, the firm's proposal also had many major and significant weaknesses and deficiencies. For example, among the major weaknesses identified in Panacea's proposal, the TEP noted that Panacea had not provided an integrated master plan, and that the firm's proposed delivery schedule was "entirely unrealistic." Id. at 101, 111. Another major weaknesses assessed by the TEP was that "Panacea [has] not demonstrated a clear understanding of the relationship of the animal models, human clinical data and correlates of protections."[5] Id. at 101. Among the significant weaknesses identified, the TEP noted that "[s]cale-up and [the] validation of the manufacturing process needs to be transferred from the India facility to the US facility. This will be a complex and time-consuming effort." The TEP also found that Panacea's "manufacturing process has not been scaled to final commercial scale." Id. at 101, 105. A number of proposal deficiencies were also identified, including that Panacea's proposal showed "a lack of understanding of how the U.S. FDA works and what is needed to gain a license in the U.S.," that there is "inexperience across management and personnel proposed with US FDA," and that Panacea's "[s]taffing plan is inadequate both in experience and numbers to support a complex, international effort of this magnitude." Id. at 103, 108.

The TEP prepared a detailed evaluation report that provided its point scoring, supported by narrative explanation, to the contracting officer. In its executive summary, the TEP noted with respect to Panacea's proposal:

> The offeror does not seem to have good understanding of the FDA process and why things are required and how long they will take; particularly evident on the mandatory criteria section. [The offeror does] not show a plan to involve FDA at regular time points throughout the process. It does not appear that the offeror understands the complexity of submitting this product to FDA and does not understand the time required to accomplish the regulatory phases of this task. The timeline to delivery is unrealistic and does not take the considerable technical and regulatory risks under consideration.

AR, Tab 12, TEP Evaluation Report, at 2. The TEP recommended to the contracting officer that only the acceptable proposals of the two highest technically rated offerors be included in the competitive range. Id. The contracting officer accepted the TEP's recommendation, and Panacea's technically unacceptable proposal was

[5] "Correlate of protection" refers to the specific immune responses induced by a vaccine that are required for a person to be protected against an infection.

excluded from the competitive range. AR, Tab 13, Competitive Range Determination, at 8. Following a debriefing, Panacea filed this protest.[6]

Panacea generally challenges the agency's exclusion of its proposal from the competitive range, arguing that the agency's technical evaluation reflected bias in favor of those firms (offerors A and B) that had proposed an rPA anthrax vaccine developed through grants from the United States government and against Panacea, which had developed its vaccine at private expense in a foreign country. Protest at 4. In this regard, Panacea argues that some of the evaluated major and significant weaknesses and deficiencies in its technical proposal reflect the agency's bias.

Although Panacea frames its arguments as being a challenge to the agency's application of an unstated evaluation factor, the crux of the protester's arguments is that HHS was biased in favor of firms that benefited from previous federal funding and against those firms (such as Panacea) that did not. Panacea, however, presents no evidence supporting this allegation other than its inference based upon the belief that some (but apparently not all) of the agency's evaluated weaknesses and deficiencies were unreasonable. We find no basis from our review of this record to conclude that the evaluation of Panacea's proposal and its exclusion from the competitive range was the result of HHS favoring firms that had earlier received funding or was otherwise motivated by bias or bad faith on the part of HHS. In this regard, government officials are presumed to act in good faith, and we will not attribute unfair or prejudicial motives to procurement officials on the basis of inference or supposition. See Shinwha Elecs., B-290603 et al., Sept. 3, 2002, 2002 CPD ¶ 154 at 5 n.6.

With respect to Panacea's challenge to the reasonableness of some of weaknesses and deficiencies evaluated in its proposal,[7] we will review an agency's evaluation and

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[6] As part of the debriefing, the agency provided Panacea with a copy of the technical evaluation report pertaining to the evaluation of its proposal.

[7] As noted above, Panacea does not challenge all of the agency's evaluated weaknesses and deficiencies in its technical proposal. Moreover, after receiving the agency's report, Panacea withdrew its objection to the agency's assessment that Panacea had not provided "a written assessment of the approach and challenges associated with an EUA or BLA (Biologics License Application] submission." See Comments at 20. In this regard, Panacea provided the declaration of a vaccine and regulatory affairs scientist (who was admitted to the protective order issued in connection with this protest as the protester's consultant); the consultant generally disagrees with the agency's decision to exclude Panacea's proposal from the competitive range but does not assert, despite his review of the protest record, that any of HHS's evaluated weaknesses or deficiencies in Panacea's proposal were unreasonable. The consultant, however, does admit that "producing a new vaccine

(continued...)

exclusion of a proposal from the competitive range for reasonableness and consistency with the solicitation criteria and applicable statutes and regulations. Novavax, Inc., B-286167, B-286167.2, Dec. 4, 2000, 2000 CPD ¶ 202 at 13. Contracting agencies are not required to retain in the competitive range proposals that are not among the most highly rated or that the agency otherwise reasonably concludes have no realistic prospect of being selected for award. Federal Acquisition Regulation (FAR) § 15.306(c)(1); General Atomics Aeronautical Sys., Inc., B-311004, B-311004.2, Mar. 28, 2008, 2008 CPD ¶ 105 at 5.

Here, Panacea first complains that the TEP chairperson's evaluation summary of Panacea's proposal under the technical merit/time line subfactor incorrectly stated that the protester had not produced bulk drug substance (BDS) of its anthrax vaccine. The protester contends that it has produced BDS at quantities as large as "[DELETED] pilot scale batches."

The agency states that the TEP recognized that Panacea had done BDS process development on a small scale and that the weakness assessed in Panacea's proposal was that Panacea had not produced BDS of its proposed vaccine at a scale required for the contract.[8] Legal Memorandum at 14. This contention is supported by the contemporaneous evaluation record. The TEP recognized that Panacea had produced BDS on a small scale, noting, as a minor strength, that Panacea proposed "[vaccine had been] scaled up to pilot scale [DELETED] in India, with current plans to scale to [DELETED] in India and then [DELETED] in US…Well characterized process at [DELETED] scale with [DELETED] batches produced." See AR, Tab 12, TEP Evaluation Report, at 104. The TEP also found, however, that Panacea had not manufactured this product on a scale that would be required for this contract. See, e.g., AR, Tab 10, Scoring Sheets of Evaluator 2, at 2 ("have not created commercial scale batches"); Tab 12, TEP Evaluation Report, at 96 ("[t]he manufacture of the product . . . has not been done at the scale required for this proposal.")

The protester responds, however, that there is "no mandatory requirement" in the solicitation for BDS production on a commercial scale and that therefore downgrading Panacea's proposal for failing to show BDS production at this scale was unreasonable. Protest at 5. We find this argument to be without merit, however, given that the RFP informed offerors that the agency would be evaluating under the technical approach subfactor whether the "[c]ontractor has demonstrated validated bulk drug substance (BDS) production at proposed commercial scale." RFP at 49.

(...continued)
in a five-year time-frame is an inherently risky endeavor." Protester's Comments, Declaration of Consultant, Dec. 1, 2008, at 2.

[8] Commercial scale production was 1500L. See Protest at 5; Panacea's Proposal at 58.

The protester also complains that its proposal should not have been downgraded for a lack of FDA experience. See AR, Tab 12, TEP Evaluation Report, at 106 ("[Panacea had a] general lack of experience with FDA across the board.") Panacea argues that, since it is a foreign firm "[DELETED] in the United States," Panacea could reasonably rely upon the experience of its four proposed subcontractors, which had "extensive" FDA experience, and that, in any case, Panacea's project director has relevant FDA experience, given that he "led the effort to obtain re-approval for BioThrax, currently the only FDA-licensed anthrax vaccine." Protest at 8-9.

As noted above, HHS downgraded Panacea's proposal because the firm had failed to demonstrate experience with, or for that matter good understanding of, the FDA and that agency's regulatory process. See, e.g., AR, Tab 12, TEP Evaluation Report, at 101, 103, 107. In this regard, the RFP informed offerors that contractors would be required to satisfy FDA requirements for "potential use of the vaccine in a [post-exposure prophylaxis] plus antibiotic scenario in a declared emergency under an EUA" and to otherwise obtain licensing in accordance with FDA regulations, and offerors were informed that the experience of their personnel to perform the contract would be evaluated. See RFP at 8, 49. The agency states that it did not credit Panacea for the FDA experience of its subcontractors because Panacea's proposal identified Panacea, and not the subcontractors, as being responsible for dealing with the FDA. We have no basis to object to this determination, given that Panacea's proposal did not identify any subcontractors to be members of its "regulatory team," which Panacea stated would deal with the FDA and be responsible for regulatory submissions. See, AR, Tab 6, Panacea Technical Proposal, at 145.

With respect to Panacea's argument that HHS unreasonably did not credit the firm for the FDA experience of its proposed project director, the record supports the agency's contention that, although this individual's resume identified experience dealing with FDA on another program, the resume did not describe or detail that experience. In this regard, Panacea's proposal does not indicate to what extent, if at all, the project director would interact with FDA, given that this person was only identified as only supporting this contract [DELETED] percent of [DELETED] time, see AR, Tab 6, Panacea Technical Proposal, at 151, and was not identified as being a member of the "regulatory team."[9]

Panacea also disagrees with the TEP's finding that Panacea had not demonstrated "an understanding of the relationship of the animal models, human clinical data and

[9] With respect to Panacea's [DELETED], who was identified as leading the regulatory team, Panacea did not provide a resume for this individual, and, in any event, [DELETED] was only proposed as providing [DELETED] percent of [DELETED] time to this contract.

correlates of protection." See AR, Tab 12, TEP Evaluation Report, at 101. Panacea essentially argues that its proposal sufficiently demonstrated this understanding. See Protest at 6-7.

HHS responds that, while Panacea provided some information in its proposal regarding historical and proposed non-clinical studies and for proposed clinical studies, the firm did not explain its studies in a way that showed how the studies would "contribute to the body of knowledge required to conclusively demonstrate a correlate of protection and efficacy of the product." Legal Memorandum at 21. HHS also states that Panacea's descriptions of its non-clinical studies and clinical studies did not show that it incorporated suggestions and recommendations of the FDA. The agency concluded:

> There was no discussion to present the critical linkages and interdependencies between non-clinical and clinical development elements, and no such linkages were evident from review of the Gantt chart/project schedule submitted. This absence of integration of key program elements, in concert with an inadequate presentation of a complete regulatory strategy, led the TEP to the conclusion that the offeror did not have a practical execution plan for the project.

Legal Memorandum at 19.

Panacea does not show that the agency's evaluation in this regard was unreasonable. Rather, in its comments, Panacea merely objects to two statements in the agency's legal memorandum with respect to whether Panacea provided "passive transfer studies" in its proposal and whether Panacea's proposal provided for studies of the vaccine at various dosages. Neither of these two concerns, however, shows that the agency's overall criticism that Panacea had failed to demonstrate an understanding of the relationship of the animal models, human clinical data, and correlates of protection was unreasonable. In any case, the agency's concern with whether Panacea had provided passive transfer studies in its proposal was only identified by the TEP to be a minor weakness. See AR, Tab 12, TEP Evaluation Report, at 103. With respect to whether Panacea's proposal provided for studies of the vaccine at various dosages, the record does not indicate, nor does the protester direct us to any place in the technical evaluation, where this had a significant impact on the TEP's evaluation of Panacea's proposal or on the agency's competitive range determination.

Finally, in its comments on the agency's report, Panacea raises numerous new challenges to the agency's evaluation. Specifically, Panacea objects to HHS"s "mechanical reliance on point scores," that standards were allegedly not established for assigning point scores, and that the assigned point scores were not adequately supported by the TEP's narrative discussion. We find that these supplemental

grounds of protest were not timely filed. Specifically, Panacea learned the bases of these protest grounds from the agency's report, which Panacea received November 20, 2008. Panacea, however, requested and received a 1-day extension of time to file its comments; an extension of time to file comments does not toll our timeliness requirements for the filing of new protest grounds. See Exelon Servs. Fed. Group, B-291934, Apr. 23, 2003, 2003 CPD ¶ 86 at 7 n.4. As a result of the extension, Panacea filed its comments on December 2, 11 days after receiving the agency report; thus, these new protest grounds were untimely filed and are dismissed. 4 C.F.R. § 21.2(a)(2). In any event, the record shows that HHS did not rely upon a mechanical application of point scores to determine which proposals should be included in the competitive range; moreover, as indicated above, the record contains substantial narrative comments detailing the offerors' respective strengths, weaknesses and deficiencies underlying the point scores.

In sum, we do not agree with the protester that the agency's exclusion of the firm's proposal from the competitive range was unreasonable, given that Panacea's proposal was reasonably found to be technically unacceptable such that it would require major revisions to be made acceptable and was significantly lower rated than the proposals that were included in the competitive range.

The protest is denied.

Gary L. Kepplinger
General Counsel