G A O
Accountability * Integrity * Reliability

Comptroller General
of the United States

United States General Accounting Office
Washington, DC 20548

Decision

Matter of: Aventis Pasteur

File: B-291584

Date: January 23, 2003

Frank M. Rapoport, Esq., and Thomas F. Burke, Esq., McKenna Long & Aldridge, for the protester.
Jonathan A. Baker, Esq., and Michael Colvin, Department of Health and Human Services, for the agency.
Linda S. Lebowitz, Esq., and Michael R. Golden, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

Protest is denied where it is clear from the record that the protester was not misled during discussions concerning the criticality of an offeror's proposed approach to satisfy the solicitation's milestone requirements.

DECISION

Aventis Pasteur protests the rejection of its proposal under request for proposals (RFP) No. NIH-NIAID-DMID-02-26, issued by the Department of Health and Human Services for the development and testing of anthrax vaccines. Aventis challenges the agency's conduct of discussions with the firm.

We deny the protest.

The RFP, issued on April 22, 2002, explained that there was an urgent need to devise appropriate and effective measures to protect the general population from the harmful effects of anthrax spores used as instruments of terror. The RFP provided that in view of the events since September 11, 2001, there was sufficient justification to warrant the rapid development, testing, and licensure of a vaccine to cover pre-exposure and post-exposure to anthrax, preferably in a single dose. Accordingly, the RFP stated that this procurement to develop, manufacture, characterize, and evaluate a pilot lot of *B. anthracis* recombinant protective antigen (rPA) vaccine would be "milestone-driven." RFP Statement of Work.

The acquisition of an anthrax vaccine would be conducted in three phases, with the first two phases covered by this RFP. Under the first phase, the agency anticipated making (in September 2002) multiple cost-plus-fixed-fee, completion-type contract awards, under which the contractors would be required to develop an anthrax vaccine in accordance with the following milestones, as described in the RFP: (1) within 3 months of award, produce a pilot lot of rPA vaccine suitable for phase 1 and optional phase 2 clinical trials;[1] (2) within 6 months of award, provide 2,000 doses of the vaccine previously developed as a pilot lot so that the agency could seek approval from the Food and Drug Administration to conduct its own clinical trials; (3) furnish protocols for phase 1 and optional phase 2 clinical trials; (4) conduct phase 1 clinical trials; and (5) within 12 months of award, provide a plan for emergency production of 25 million doses of the vaccine previously developed as a pilot lot. The RFP provided that the milestones were considered contract deliverables. Under the second phase, an option under this RFP, the agency would select one of the multiple awardees from the first phase to conduct phase 2 clinical trials.[2]

The RFP provided that the awards would be made to the offerors whose proposals represented the best overall values to the government, considering technical evaluation factors and cost. The technical evaluation factors included technical approach (70 points), personnel (15 points), and facilities (15 points). Under technical approach, the following areas would be evaluated: (1) technical adequacy and feasibility of proposed plan to develop candidate vaccine with attributes included in the statement of work (30 points); (2) technical adequacy and feasibility of proposed process development plan leading to the manufacture of required amounts of vaccine approved for emergency use within the specified time mentioned in the statement of work (30 points); and (3) technical adequacy and feasibility of clinical development plan, including proposed protocols for phase 1 and phase 2 clinical trials as described in the statement of work (10 points). The RFP provided that the technical evaluation factors were significantly more important than cost.

Four firms, including Aventis, Avecia, Ltd., and VaxGen, Inc., submitted initial proposals by the closing time on June 6. As relevant here, Aventis proposed an rPA

---

[1] Phase 1 clinical trials involve introducing a drug into people in order to gather metabolic and pharmacologic data, as well as to study the side effects of escalating doses and to glean preliminary information on effectiveness. Phase 2 clinical trials study the efficacy of a drug and assess its short-term side effects. Legal Memorandum at 3 n.2.

[2] For the third phase, this RFP announced that the agency intended to issue, on a full and open competitive basis, a solicitation for the production and acquisition of an anthrax vaccine; participation in the procurement under protest here will not be a prerequisite for participating in the production/acquisition procurement.

vaccine produced by [deleted] to support the phase 1 clinical trials. Aventis described items (e.g., yield, expression level, and production process) that would be "optimized and scaled-up in order to meet future demand," and it also stated that ten extraneous amino acid residues would be removed from the [deleted] vaccine. Aventis Initial Proposal, at 1-24.

The agency's technical evaluation panel assigned the Aventis initial proposal a score of 89 out of a possible 100 points, the highest technical score received. (The other scores ranged from 56 to 64 points.) Despite this score, the evaluators determined that there were a number of technical weaknesses and disadvantages in the Aventis proposal. For example, while noting that Aventis suggested that considerable additional work in a number of areas would be needed before large-scale production could be initiated, and recognizing that this additional work would optimize the final production and possibly the final product, the evaluators nevertheless were concerned that a delay in any one of the areas requiring additional work could affect the ability of Aventis to meet the expected timelines. In addition, since the vaccine used in the phase 1 clinical trials would be structurally different from the vaccine expected to be manufactured as the final product (as a result of removing the extraneous amino acids), the evaluators expressed some concern that the preclinical and clinical findings with the predecessor vaccine would not predict the behavior of the production vaccine. Technical Evaluation Report for the Aventis Initial Proposal, at 34-35, 37, 40.

The contracting officer included all four of the initial proposals in the competitive range. On August 5, the contracting officer conducted written discussions with Aventis. With respect to its technical approach, the contracting officer noted that the evaluators had "comments and concerns regarding the product proposed for use in the Phase 1 study [and the ability of Aventis] to meet the RFP milestones." For example, the contracting officer pointed out to Aventis that any delays in the additional work identified as necessary to optimize trial production and possibly the final product could affect the ability of Aventis to meet expected timelines. As a result, the contracting officer requested that Aventis provide a clear timeline based upon previous experience with product development and provide a risk management plan addressing each critical phase. The contracting officer also pointed out to Aventis that the vaccine proposed for the phase 1 clinical trials was different from the final product (as a result of having to remove the extraneous amino acids) and that there was concern that preclinical and clinical findings with the phase 1 product might not predict behavior of a future product; as a result, the contracting officer requested that Aventis address how quickly information would be obtained using the appropriate product that would be taken forward to licensure. E-mail with Attach. from Contracting Officer to Aventis, Aug. 5, 2002.

On August 6, the contracting officer furnished to Aventis a list of supplemental technical issues to be addressed by the firm. In relevant part, the contracting officer stated that

> [t]he reviewers found that significant optimization with the product appears to be required prior to large-scale manufacturing. The statement on page ATC-6[,] " . . . represents substantial progress toward completion of Milestone 2[,]" appears misleading, in that the proposed ability to meet several early milestones appears to be both artificial and based upon a sub-optimal and ill-defined product. . . . In addition, pages 1-14/25 cite proposed changes to the construct and require establishing new expression systems and purification schemes. Given this approach, the product development appears to be immature. Given that the current Phase 1 material lacks an efficient expression system and a manufacturing process with acceptable yield, the government has no interest in receiving 2,000 doses of the same material. Please review the overall approach and timeline to determine if clinical trial data can be produced by December 2003, using vaccine material produced with methods now being optimized. . . . The Government appreciates the significance of this request, but believes the likelihood of attaining solicitation milestones post-award would be enhanced by this approach.

E-mail with Attach. from Contracting Officer to Aventis, Aug. 6, 2002.

On August 13, Aventis responded to this supplemental technical question, expressing surprise that by asking that question, the contracting officer had "essentially rejected [the firm's] project plan." In relevant part, Aventis stated that

> according to our plan and approved resources, it is not feasible to complete the Phase 1 clinical study using the new rPA clone and production process by the requested December 2003 date. Based on our experience, we are simply unwilling to state that the work will be completed by December, 2003, in order to be awarded this contract, when we know this is unlikely. The current best estimate is that the 2,000 doses of [current good manufacturing process] rPA to begin this study would not be available until [the first quarter], 2004. Of course, expanded resources ([full-time equivalent personnel] and budget) and the acceptance of more risk (e.g., using smaller scale lots) could compress this timeline by several months. Our literal interpretation, however, is that the new Aventis Team timeline fails to meet expectations of [the agency] and now places us outside the competitive range.

E-mail from Aventis to Contracting Officer, Aug. 13, 2002.

On August 14, the contracting officer responded to Aventis, explaining that the August 6 supplemental technical question was not meant to be a rejection of the firm's project plan and that it was not the government's intent to ask Aventis to submit a new proposal. Rather, as explained by the contracting officer, the purpose of the referenced question was to clarify the evaluators' concerns related to the technical evaluation factors, with specific focus on the need to ensure that the product would be far enough along in development to meet the requirements of the government as specified in the RFP's statement of work. E-mail from Contracting Officer to Aventis, Aug. 14, 2002.

On August 22, the contracting officer requested that Aventis submit its final proposal revision (FPR). On August 29, Aventis submitted its FPR. In the executive summary, Aventis stated:

> The insightful series of technical questions that we have received from the [agency's] review panel has persuaded the Aventis Team to substantially modify its original Anthrax Proposal. Of the two sets of technical questions, those that we received on August 6th were the most challenging, since they questioned three fundamental aspects relating to the competitiveness of our proposal. First, the reviewers correctly pointed out that our current rPA construct produced at [deleted] expressed low levels of recombinant product with extraneous amino acids that would require substantial changes to its sequence and purification protocol, as we moved forward. Second, the reviewers suggested that the 2,000 doses of vaccine that we intended to produce under contract by [deleted] in [the fourth quarter], 2002 were not truly representative of the rPA vaccine that will eventually be developed. In fact, it was stated categorically that the Government had no interest in receiving the vaccine which would be produced by [deleted].
>
> . . . . .
>
> As a result of [the agency's] constructive input, the Aventis Team has substantially modified [its] proposal [by proposing a vaccine that Aventis itself has been researching and developing].
>
> . . . . .
>
> Obviously, incorporating such substantial changes has impacted both our timelines and our budgets. Currently, we expect Milestone 1 to be completed in [the fourth quarter], 2003. This is approximately 12 months later than the original proposal. Milestone 2 will be completed in [the first quarter], 2004, a difference of 12 months from the original proposal. Milestone 3 will be completed in [the first quarter], 2005. Milestone 4 will be completed in [the first quarter], 2006. This is approximately 20 months later than originally proposed.

> Milestone 5 will be completed by [the fourth quarter], 2003, as originally planned.

Aventis FPR, at E-1,-2.

The agency's source selection group evaluated FPRs, assigning the Aventis FPR a score of 83 out of a possible 100 points. (The Aventis FPR received the second-highest technical score; the other scores ranged from 59 to 87 points.) The evaluators commented that the Aventis FPR offered a "significant change that jeopardized seriously the chances of meeting the ambitious timelines." Source Selection Group Summary of the Aventis FPR, Sept. 10, 2002, at 6. The evaluators pointed out that in response to questions raised about the appropriateness of the proposed pilot lot of rPA vaccine, Aventis withdrew its initially proposed pilot lot from consideration, agreeing with the criticism that the [deleted] pilot lot would have to be modified significantly before it was a candidate to be developed fully to meet the RFP goals. Id. The evaluators summarized their view of the Aventis FPR as follows:

> A principal question was raised in the primary review regarding the appropriateness of the [deleted] pilot lot of rPA, and [Aventis] agreed in the FPR that it would have to be modified considerably to qualify for the product to be taken into production. The responses were frank, but not reassuring. The reviewers did not agree that the [deleted] lot was an adequate pilot lot for the purposes of this RFP, and since [Aventis] was unable to rely on the [deleted] lot of rPA to meet early milestones of the project[,] the technical adequacy and feasibility of the proposed plan to develop a candidate vaccine with the attributes requested is weakened considerably. The offeror provided encouraging evidence that a sufficiently modified rPA had been under the early stages of product development, but the revised proposal failed to suggest these early successes would be accelerated through the product development and scale-up process. Without accelerating the product development process, which appeared to be technically feasible, it is not possible to meet the timelines imposed by the RFP. The score for this evaluation criterion was reduced because the new information provided indicated the offeror could not meet the milestone timelines.

Id. at 7.

Despite these concerns, the source selection authority made a preliminary determination to award contracts to Aventis, Avecia, and VaxGen. Source Selection Decision, Sept. 16, 2002. (No award notices were issued at this time.)

On September 17, in response to a question from the contracting officer on when Aventis intended to deliver on milestone 1 (under the RFP, within 3 months of

award, the contractor was to provide a pilot lot of rPA vaccine), Aventis appeared to take exception to milestone 1. E-mail from Aventis to Contracting Officer, Sept. 17, 2002. Accordingly, on September 18, the contracting officer advised Aventis that additional discussions with the firm were necessary in order to address, among other things, discrepancies related to the milestone delivery dates proposed by Aventis in its FPR versus those listed in the RFP's statement of work. E-mail from Contracting Officer to Aventis, Sept. 18, 2002.

On September 25, during a conference call, the agency explained that the urgency of this procurement did not permit flexibility regarding delivery of the requirements. With reference to its FPR, Aventis acknowledged that milestones 1, 2, and 4 would be delayed 1 year beyond the times stated in the RFP; Aventis nevertheless requested that its FPR be considered under modified (i.e., relaxed) milestone requirements. Agency Summary of Conference Call, Sept. 25, 2002.

On September 30, Aventis submitted a written follow-up to the September 25 conference call. Aventis stated that based on the status of the pre-award work and the government's rejection of the [deleted] approach to meet the milestone dates, Aventis "[did] not believe, as set forth in the FPR, that the milestone dates [could] be met by anyone." Aventis Letter to Contracting Officer, Sept. 30, 2002. Aventis reiterated its position that the "proposed milestone dates [were] not consistent with delivering a scaleable quality product to meet the ultimate goal, the 25 million dose National Emergency Stockpile. [Aventis would] not commit [itself] to delivering something [it did] not believe . . . [was] possible." Id. Aventis stated that it "fail[ed] to see how meeting each of the milestones, within the timeframe suggested by the RFP, [was] necessary and sufficient to meet the overriding objective of [the agency] in providing a reliable source of rPA vaccine for the stockpile." Id.

By letter dated October 2, the agency advised Aventis that its proposal was being eliminated from further consideration because the firm would not be able to meet the milestones set forth in the RFP and that a delay of up to 12 months was unacceptable for vital research. On October 3, at the direction of the source selection authority, the contracting officer amended the source selection document by removing Aventis as one of the awardees because of, among other things, the firm's inability to reconcile its proposed milestone schedule with the requirements of the RFP. On the same day, the agency announced that awards had been made to Avecia and VaxGen.

Aventis, which does not dispute that under its FPR, it would be unable to satisfy the RFP's stated milestones, Protester's Comments, Dec. 2, 2002, at 4-5, argues that it was misled during discussions to replace its highly rated, technically acceptable approach as contained in its initial proposal with an approach that was more time-consuming. This argument, however, is belied by the underlying contemporaneous record.

Here, the RFP's statement of work provided that this procurement was "milestone-driven" and clearly detailed the requirements under each of five stated milestones. Moreover, the RFP's evaluation scheme made specific reference to the statement of work requirements, which included the five milestones.[3] In its initial proposal, Aventis proposed a vaccine produced by [deleted]. While the technical approach described in the Aventis initial proposal received the highest technical rating, this approach was also determined to have numerous technical weaknesses and disadvantages, including the need to modify the proposed [deleted] vaccine in a number of respects before large-scale production could begin, with the risk that the modifications could delay the ability of Aventis to meet the milestones set forth in the RFP.

As detailed above, during discussions, Aventis was advised of specific agency concerns with the [deleted] vaccine proposed by the firm for use in the phase 1 clinical trials and with the ability of Aventis to satisfy the RFP's milestone requirements. Contrary to the position taken by Aventis in this protest that it was misled during discussions, Aventis, in its FPR, characterized the agency's discussion questions as "insightful" and "constructive," conceding that the [deleted] vaccine would not be representative of the vaccine that would eventually be developed and recognizing that the agency had no interest in receiving the [deleted] vaccine. In its FPR, Aventis revised its technical approach, proposing a vaccine that was in the early stages of product development and that would lag approximately 1 year behind the milestones required by the RFP. The agency ultimately downgraded and rejected the Aventis FPR because Aventis failed to address how the product development process for the newly proposed vaccine would be accelerated in order to meet the RFP's milestones.

It is clear from this record that Aventis was not misled during discussions concerning the agency's critical need for an offeror's proposed technical approach to satisfy the RFP's milestones. After being advised during discussions of technical weaknesses and disadvantages in its initial proposal as they related to the milestones described in the RFP, Aventis modified its proposed technical approach in a manner that clearly took exception to the RFP's milestone requirements, apparently based on its hope that the agency would ultimately relax these requirements.[4] On this record, Aventis has not made any credible argument to support its current position that it was misled during discussions. Accordingly, we have no basis to question the

---

[3] To the extent Aventis questions the materiality of the RFP's "milestone-driven" requirements, this argument constitutes an untimely challenge of an alleged solicitation impropriety. Bid Protest Regulations, 4 C.F.R. § 21.2(a)(1) (2002).

[4] The record shows that even after Aventis submitted its FPR, the agency conducted discussions with Aventis in order to obtain a conforming proposal from the firm.

agency's decision to reject the FPR submitted by Aventis because of the firm's failure to submit a proposal that would satisfy the express terms of the RFP.[5]

The protest is denied.[6]

Anthony H. Gamboa
General Counsel

[5] While Aventis makes much of the fact that the agency initially had determined to include the firm as one of the multiple awardees, we conclude that the agency reasonably determined that an award to Aventis would not be in accordance with the terms of the RFP because the firm took exception to the RFP's milestone requirements.

[6] Aventis has raised other collateral issues and arguments, each of which we have considered and find without merit.