149760

Comptroller General
of the United States
Washington, D.C. 20548

Decision

Matter of: Impact Instrumentation--Reconsideration

File: B-250968.3

Date: August 9, 1993

Daniel A. McNulty, Esq., Seyfarth, Shaw, Fairweather & Geraldson, for the protester.
Glenn G. Wolcott, Esq., and Paul I. Lieberman, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

Prior dismissal of protest issue as untimely was proper where the issue was first raised more than 10 days after the protester knew or should have known of the basis for protest.

DECISION

Impact Instrumentation, Inc. requests reconsideration of our decision, Impact Instrumentation, Inc., B-250968.2, Mar. 17, 1993, 93-1 CPD ¶ 241, in which we denied in part and dismissed in part Impact's protest challenging the Defense Logistics Agency's (DLA) award of a contract for portable ventilators to Bird Products Corporation under request for proposals (RFP) No. DLA120-92-R-0019. Impact contends that we erroneously dismissed a portion of its protest as untimely and, alternatively, requests that we consider the dismissed issue under the "significant issue" exception to our timeliness rules.

We deny the request for reconsideration.

BACKGROUND

Under the procurement at issue, DLA sought firm, fixed-price proposals for a quantity of portable ventilators to assist patient respiration. Among other things, the solicitation called for offerors to comply with Section 510(k) of the Federal Food, Drug and Cosmetic Act (FFDCA) with regard to obtaining premarketing approval from the U.S. Food and Drug Administration (FDA) for the proposed ventilators. See 21 U.S.C. § 360(e) (1988).

Both Impact and Bird timely submitted initial proposals and, subsequently, best and final offers (BAFOs). Impact proposed its Uni-Vent, model 750, for which it had previously obtained FDA premarketing approval. Bird proposed a modified version of its model 6400ST. Bird had previously obtained FDA premarketing approval for the model 6400ST; its proposal stated that FDA approval for the modified version of the model 6400ST would be obtained upon award of the contract. Bird's proposal offered a total price of $9,783,280; Impact's proposal offered a total price of $15,239,900.

On October 7, the agency awarded a contract to Bird. On October 16, Impact filed its initial protest challenging various aspects of that award. Among other things, Impact maintained that the specific language of the solicitation and its incorporation of the requirements of Section 510(k) of the FFDCA required that offerors obtain FDA approval of their proposed products prior to submitting proposals, and that the FDA had not granted such approval for Bird's proposed ventilator. In relevant part, Impact stated:

> "The specific language of Section K of the RFP at 141 requires that the offeror must be in compliance with Section 510(k) of the [FFDCA] regarding the proposed ventilator. In addition, the offeror is required to provide the Pre-market Notification Approval Number [issued by FDA] for the proposed ventilator. Clearly, 510(k) approval is required before submission of the offer.
>
> "In the instant case, Bird has not received 510(k) approval for its proposed ventilator and therefore could not have had the required approval prior to the submission of the offer. Impact asserts that this is a patent failure to meet the requirements of . . . the RFP."

By letter dated October 26, 1992, Bird responded to Impact's protest, stating, among other things, that: "Bird, in fact has filed for 510(k) approval on its proposed device on October 26, 1992." On November 20, the agency responded to all of the various issues raised in Impact's protest.

On December 8, Impact filed its comments responding to the agency report; in those comments, Impact for the first time asserted that DLA's award to Bird was improper because Bird had not filed an application for FDA approval of its modified ventilator 90 days prior to submitting its proposal. In its December 8 comments, Impact specifically distinguished this allegation from that raised in its initial protest, stating:

> "While Impact still contends that Bird was required to receive 510(k) approval prior to the offer, whether Bird received this approval prior [to submitting its offer] is of no consequence to its failure to comply with its obligation under [the FFDCA] to submit its 510(k) notice 90 days prior to offer." (Emphasis added.)

PRIOR DECISION

In our prior decision, we concluded that, under the language of this solicitation, FDA's approval of the product Bird proposed was a matter of responsibility and that such approval need only be obtained prior to the commencement of contract performance. Impact Instrumentation, Inc., supra; see also Physio Control Corp.; Medical Research Laboratories, Inc., B-231999.2; B-231999.3, Aug. 10, 1989, 89-2 CPD ¶ 123.

Regarding Impact's argument that the award was improper because Bird had not submitted an application to the FDA 90 days prior to submitting its proposal to DLA, we dismissed that portion of Impact's protest on the basis that the issue was not timely raised. 4 C.F.R. § 21.2(a)(2) (1993). Specifically, the record established that Impact learned on October 29 that Bird had not filed an application for its modified ventilator until after contract award, but Impact failed to raise that issue as a basis for protest until more than a month later, after DLA had submitted its agency report.

Impact requests reconsideration of our partial dismissal of its protest.

DISCUSSION

Impact first argues that its protest regarding Bird's failure to submit an application should be considered as having been raised in its general allegation that Bird failed to comply with the requirements of Section 510(k) of the FFDCA. We find this argument without merit.

A bid protest must set forth a detailed statement of the legal and factual grounds of protest. 4 C.F.R. § 21.2(b)(4) (1993). Where a protester, in its initial protest, presents arguments in general terms and then, in its comments on the agency's report, for the first time details alleged procurement deficiencies, the detailed arguments will not be considered unless they independently satisfy the timeliness requirements under our Bid Protest Regulations. Astro-Med, Inc., B-232147.2, Nov. 1, 1988, 88-2 CPD ¶ 422; Dayton T. Brown, Inc.--Recon., B-223774.4, Jan. 21, 1987, 87-1 CPD ¶ 75.

Here, Impact's initial protest did not allege that the procurement was flawed due to Bird's failure to apply for FDA approval of its modified ventilator; rather, as noted above, Impact's initial protest was specifically based on the allegation that the FDA had not granted approval for the modified ventilator before Bird's proposal was submitted. Consistent with Impact's protest, DLA's agency report addressed the required timing for obtaining FDA approval, but did not discuss whether Bird was required, as Impact subsequently alleged, to have applied for approval at a particular point in time preceding the submission of its proposal. As noted above, Impact's own comments on the agency report expressly recognized the difference between the two issues, stating that resolution of the first issue (obtaining FDA approval) was "of no consequence" to Bird's failure to submit an application for FDA approval 90 days before submitting its proposal.

Impact's allegation regarding Bird's allegedly belated FDA application constitutes an issue which is separate and distinct from Impact's initially raised issue regarding the required timing for obtaining FDA approval. Accordingly, our prior decision properly dismissed as untimely the issue regarding the required timing for Bird's application to the FDA because it was first raised in Impact's December 8 comments on the agency report.

Alternatively, Impact argues that the reason it did not initially raise the issue of the required timing for Bird's FDA application was that Impact did not learn of Bird's allegedly belated application until Impact received the agency report on November 20. Impact's assertion in this regard is inconsistent with its first argument that it did, in fact, raise this issue in its initial protest, and is also contradicted by the record.

As noted above, Bird's letter of October 26 responding to Impact's protest specifically stated: "Bird, in fact, has filed for 510(k) approval on its proposed device on October 26, 1992."[1] Further, Impact's comments of December 8 specifically identified Bird's October 26 letter as the basis for its factual assertion that Bird belatedly filed its application, stating:

> "Bird conceded [that a new application for the modified model 6400ST was necessary] when it filed a new 510(k) application, after Impact's protest, on October 26, 1992. (Agency Report, Tab 38)."

---

[1]The record contains Impact's express statement acknowledging that it received this letter on October 29.

Tab 38 of the agency report contained only Bird's letter of October 26. Obviously, Impact had actual knowledge of this basis for protest on October 29, when it received Bird's letter.

Finally, Impact argues that we should consider the issue regarding Bird's FDA application under the "significant issue" exception to our timeliness rules, 4 C.F.R. § 21.2(c). We decline to do so. Application of the "significant issue" exception to our timeliness rules is limited to untimely protests that raise issues that have not been considered on the merits in a previous decision and are of widespread interest to the procurement community. See, e.g., DynCorp, 70 Comp. Gen. 38 (1990), 90-2 CPD ¶ 310. As we noted in our prior decision, subsequent to issuing this solicitation, DLA adopted a new standard clause for use in subsequent procurements of this type. The new clause explicitly requires rejection of proposals that do not have FDA approval 90 days prior to submission of the initial offer or the original closing date, whichever comes first. Clearly, the new clause eliminates the issue regarding the requirement to submit an application 90 days prior to proposal submission; hence, the issue cannot be of widespread interest to the procurement community.

The request for reconsideration is denied.

for James F. Hinchman
General Counsel