Lieberman 24574

DECISION

THE COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

FILE: B-208035 **DATE:** March 22, 1983

MATTER OF: Propper Manufacturing Co., Inc.

DIGEST:

1. Protest was timely filed under GAO Bid Protest Procedures where, within 10 working days after protester received notice of basis of protest, it filed letter with agency indicating that it took exception and requested corrective action by agency and subsequently filed its protest with GAO within 10 working days after being notified that the agency had denied its initial protest.

2. Agency determination that a small business is nonresponsible based on a negative recommendation for lack of available data, contained in a Food and Drug Administration quality assurance survey must be referred to the Small Business Administration for consideration under the certificate of competency procedures.

3. Claim for proposal preparation costs is denied where it cannot be determined that the protester had a substantial chance of receiving the award.

Propper Manufacturing Co., Inc. (Propper), protests the award of a requirements contract for occult blood determination test kits to Smithkline Diagnostics (Smithkline) under solicitation No. DLA120-82-R-0656, issued by the Defense Logistics Agency (DLA). Propper, a small business concern, asserts that it was the low responsible offeror, but was improperly rejected as nonresponsible by DLA without the requisite referral of the matter to the Small Business Administration (SBA) for consideration under the certificate of competency (COC) procedures.

We sustain the protest.

Propper's best and final offer under the solicitation was low at $11.08 per unit and Smithkline's was the next low apparently acceptable offer at $14.60 per unit. Since Propper was the low offeror, DLA ordered a preaward survey. A preaward survey conducted by the Defense Contract Administration Services resulted in a favorable recommendation.

Under a 1981 Interagency Agreement between the Department of Defense (DOD) and the Food and Drug Administration (FDA), the FDA assumed quality assurance responsibility for DOD contracts for medical devices as defined by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq. (1976) (FDC Act). This agreement gives FDA the primary responsibility for the performance of the quality assurance portion of preaward surveys relating to such devices and the responsibility for the administrative interpretation and enforcement of the FDC Act. FDA, at the request of DOD, reviews the capability of suppliers to produce devices of an appropriate quality whenever these suppliers are being considered by DOD for award of a contract. During the quality assurance portion of the preaward survey, FDA is to ascertain whether the supplier has the capability to produce the supplies in question with a quality level conforming to the applicable purchase documents. Under the terms of the agreement, the FDA is obligated to recommend a firm as nonacceptable for a contract if it is not possible for FDA to properly evaluate the firm's capability to furnish the product, and the actual determination of contractor responsibility is explicitly reserved for DOD. DOD performs the nonquality portions of the preaward surveys.

In this instance, the FDA preaward quality assurance survey resulted in a finding that FDA could not recommend Propper for procurement of the test kits. In particular, FDA stated:

> "We are unable to complete our evaluation. [Propper] was not in operation with respect to this product. They intend to be in production in approximately one month. Stability data provided was from the raw material manufacturer * * * and did not represent the firm's product in the final container closure system. We cannot recommend this firm for procurement of this item at this time."

Based on FDA's recommendation, the DLA contracting officer determined that Propper should be rejected as nonresponsible on the ground that Propper did not have stability data to support the 32-month expiration dating period for the test kits required under the solicitation, and, therefore, failed to comply with the requirements of the FDC Act. The contracting officer further determined that since the rejection came within the meaning of Defense Acquisition Regulation (DAR) § 1-903.1(v) (which requires that a contractor be qualified and eligible to receive an award under applicable laws and regulations), the nonresponsibility determination was exempted from referral to the SBA for COC consideration under DAR § 1-705.4(c)(5), which provides that referral need not be made to the SBA if a contracting officer determines a small business concern nonresponsible pursuant to § 1-903.1(v) and the determination is approved by head of the contracting activity or his designee.

Award was made to Smithkline on April 13, 1982. In response to a letter from Propper of April 16, 1982, DLA requested a reevaluation from FDA regarding its negative preaward survey report. FDA responded to DLA on June 4, 1982, stating that in its onsite inspection conducted on February 22, 1982, it was advised by Propper's management that Propper had no stability data covering its own product. Data was furnished from the firm from which Propper purchases raw materials, but there was no documentation that this data would represent the finished product test kit that Propper planned to produce and supply. In addition, there were basic deficiencies in the stability data which was provided that would have made it incomplete and inadequate even if it represented the Propper-produced, finished product. FDA further indicated that it had made only one request to Propper for the stability data, which is FDA's standard practice, and it confirmed the correctness of the earlier preaward quality assurance evaluation which it had furnished to DLA on March 8, 1982.

In fact, FDA did continue to review Propper's product, but it did not determine it to be acceptable with respect to stability data until June 30, 1982, more than 2-1/2 months after the award was made by DLA.

In considering this protest, we solicited and obtained the views of both FDA and SBA.

As a threshold matter, DLA asserts that the protest is untimely because it was not filed with DLA or with GAO until more than 10 working days after Propper had been notified of the award to Smithkline and of the fact that Propper had been rejected as nonresponsible by DLA.

On April 16, 1982, DLA provided this information to Propper. As noted above, by letter to DLA of April 19, 1982, Propper took exception to DLA's determination. In response, DLA agreed to resubmit the matter to FDA. DLA correctly points out that Propper's April 16 letter stated that it "plans to protest the contract award," rather than that it protests the award. However, we believe that this letter clearly indicated Propper's present intention to file a protest and itself constituted a protest to the Agency. We have held that the protester need not expressly state that it "protests"; rather, the intent to protest may be conveyed by an expression of dissatisfaction and a request for corrective action. Prosearch, B-206316, June 30, 1982, 82-1 CPD 636. Propper's April 16 letter also states that it "requests that [DLA] not issue any orders under the Smithkline contract until Propper's protest is resolved." Moreover, in DLA's letter of April 26, 1982, to Propper, DLA acknowledges receipt of Propper's letter "notifying us of your protest of award." Thereafter, it is undisputed that Propper timely filed a protest in our Office within 10 working days after learning of the subsequent adverse agency action, as required by our Bid Protest Procedures, 4 C.F.R. § 21.2(a) (1982).

While Propper has raised a number of subsidiary issues, its main basis of protest concerns the failure of DLA to refer the matter to SBA for consideration under the COC procedures. DLA contends that the Small Business Act, 15 U.S.C. § 637(b)(7) (Supp. I, 1977), does not require referrals to SBA of nonresponsibility determinations based upon conclusions made by FDA that a concern is not in compliance with its regulations. SBA argues that the Small Business Act does not permit any exceptions to the COC referral requirement. SBA acknowledges that it could not supplant FDA's finding with respect to product quality assurance, but argues that it should be able to insure that the small business firm was afforded procedural due process in the course of the evaluation procedure. Finally, Propper cites our decision, International Business Investments, Inc.; Career Consultants, Inc., 60 Comp. Gen. 275 (1981), 81-1 CPD 125 (IBI), in support of its argument that no exemption from referral to the SBA is permissible. Propper

points out that in IBI we explicitly held that the DAR § 1-705.4(c)(5) exception from the requirement for COC referral was impermissible under the Small Business Act and under SBA's final implementing rules, 13 C.F.R. § 125.5 (1982), and we recommended revision of the DAR to eliminate the exception and interim advice to contracting activities to follow our holding that COC referral was required pending this revision. In addition, Propper argues that our decision, Paramex Labs, Inc., B-205826, March 16, 1982, 82-1 CPD 249, provides specific support for its argument that this nonresponsibility determination based on an FDA finding must be referred to the SBA.

We agree with SBA and Propper.

As DLA correctly points out, our Office does not review protests involving the rejection of a bid because of nonconformance with a requirement within the cognizance of the FDA. Carlisle Laboratories, Inc., B-186987, et al., February 22, 1977, 77-1 CPD 124; Lemmon Pharmacal Company, B-189048, July 25, 1977, 77-2 CPD 47. However, this is not the relevant issue in this instance. Propper's rejection was based on the contracting officer's nonresponsibility determination, which in turn was derived from FDA's statement that it could not recommend Propper for award. However, FDA's statement was based on its obligation under the agreement to so recommend because of the unavailability of data needed for evaluation at the time the recommendation was made. Moreover, as DLA concedes, the FDA recommendation was not binding on the contracting officer. While the DLA contracting officer contends that he could not have found Propper responsible without supplanting the FDA's statutory authority, we do not believe this to be the case. FDA did not find or recommend that Propper's product be considered unacceptable under the FDC Act. This detemination was made by the DLA contracting officer, and reflects his interpretation of the meaning of FDA's statement that insufficient data was available to permit a favorable recommendation.

In any event, even if the FDA had explicitly found that Propper could not conform to the expiration dating requirement, the contracting officer could have determined that Propper would be likely to be able to comply with the requirement by the time of performance and, therefore, could have awarded to the firm. This would not have excused the firm from compliance with any FDA regulations, or with the FDC Act. The only issue would be one of timing, and as we indicated in IBI, if the firm was not in compliance at the

time that performance was due, the contracting activity would have the option of considering the possibility of termination.

Thus, since in reality the contracting officer and not the FDA had the right and discretion to make the responsibility determination in this instance, having made the nonresponsibility determination regarding a small business, it follows that under the Small Business Act, referral to SBA for consideration for a COC was mandated. As the SBA concedes, it could not supplant an FDA finding with respect to quality assurance. However, as we indicated in IBI, it would be appropriate for SBA to consider the timing aspects, that is, the likelihood of the firm's being in compliance with the expiration dating requirement by the time of performance. We note that after referral to SBA, under DAR § 1-705.4(c), the contracting activity is obligated to withhold award only "until SBA action concerning issuance of a COC or until 15 working days after the SBA is so notified, whichever is earlier." Obviously, neither DLA nor SBA would sanction the delivery of deficient medical supplies.

We sustain the protest.

Since award to Propper under this solicitation is not possible because the contract has been substantially performed, we will consider Propper's claim for proposal preparation costs.

We have concluded that the rejection of a low bid submitted by a small business on the basis of nonresponsibility determination without referral to the SBA was unreasonable and tantamount to arbitrary or capricious action. See Environmental Growth Chambers, B-201222, October 8, 1981, 81-2 CPD 286. In this instance, we believe that the same conclusion is applicable, particularly in view of the Paramex and IBI decisions. However, before preparation costs can be allowed, it must be determined that Propper had a "substantial chance" of receiving the award of the contract. Here, we cannot determine that Propper had a substantial chance of receiving the award. We know that a 2-1/2 month period elapsed before FDA found that Propper met the expiration dating requirement, and we are unable to determine that Propper could have been able to establish that it could satisfy this requirement before deliveries were required under the contract, had referral been made to SBA. Therefore, Propper is not entitled to preparation costs. International Limousine Service, B-206708, July 26, 1982, 82-2 CPD 77.

Because of our decision sustaining Propper's protest, we have not addressed Propper's contentions regarding several relatively minor ancillary issues.

Finally, by letter of today to the Director, Defense Logistics Agency, we are bringing this matter to the Director's attention so that action can be taken to preclude a recurrence of this deficiency.

Milton J. Socolar

for Comptroller General
of the United States