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Comptroller General
of the United States

Washington, D.C. 20548

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Decision

Matter of: Surgical Instrument Company of America

File: B-256169

Date: May 6, 1994

DECISION

Surgical Instrument Company of America protests the award of a contract for a quantity of sphygmomanometers[1] under request for proposal (RFP) No. DLA120-93-R-0278, issued by the Defense Personnel Support Center (DPSC). The protester argues that the agency improperly rejected its offer as noncompliant with the pre-marketing requirements of the solicitation.

We dismiss the protest.

The RFP, as issued on January 26, 1993, required offerors to comply with Section 510(k) of the Federal Food, Drug and Cosmetic Act (FFDCA) with regard to obtaining pre-marketing approval from the Food and Drug Administration (FDA) for the proposed sphygmomanometers. See 21 U.S.C. § 360(e) (1988). To demonstrate compliance with the FFDCA requirements, the pre-market notification clause of the RFP, 52.210-9P14, required offerors to insert the notification number assigned by the FDA and the date on which approval was granted or provide the specific basis for exemption from the FFDCA requirements. More specifically, the pre-market notification clause in the solicitation explicitly requires rejection of offers of medical devices that do not have FDA approval 90 days prior to submission of the initial offer or the original closing date, whichever comes first.

Five proposals were received and evaluated by the agency; thereafter, best and final offers were requested and received. As part of a pre-award quality assurance evaluation of SICOA,[2] the agency's quality assurance evaluator recommended an FDA survey because the firm had

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[1]A sphygmomanometer is a medical device used for measuring blood pressure. The sphygmomanometers sought under this RFP are commercial medical devices sold to the general public.

[2]For reasons not germane to this protest, the three lower-priced offers were rejected by the agency.

never supplied this item to DPSC and therefore had no quality assurance history. By letter of August 20, FDA determined that SICOA did not have Section 510(k) approval for the sphygmomanometers and recommended against award to that firm.

By letter dated August 31, DPSC notified SICOA, the low evaluated offeror in line for award, that the firm was determined ineligible for award because it was not in compliance with the FFDCA requirements and that award was made to W.A. Baum Company, Inc. On September 1, SICOA timely filed an agency-level protest against DPSC's actions, contending that as a manufacturer of these medical devices since 1969 the firm properly was exempt from the pre-market notification requirements of the FFDCA.[3] In response to SICOA's agency-level protest, the agency forwarded a copy of the protest and supporting documentation to the FDA for their review and notified the protester of their referral to the FDA. The FDA responded to the agency by letter dated September 22 that since SICOA did not furnish any documentation to show that it had produced and sold these medical devices prior to the May 28, 1976, enactment date of Section 510(k), FDA found SICOA's claim of pre-amendment exemption was insupportable. Relying on this response from the FDA, DPSC dismissed SICOA's protest by letter dated September 23.

After receiving the agency's response to its first protest, SICOA filed a second agency-level protest, by letter dated September 30, which again challenged the FDA's determination that SICOA does not qualify for the pre-amendment exemption. In that second protest letter, SICOA stated that based on continued discussions with the FDA, the firm was "preparing" another affidavit for submission to the FDA. On October 4, SICOA furnished additional information to the FDA to support its request for further review of its status under Section 510(k) of the FFDCA. In a letter dated December 14, the FDA determined that the materials submitted by SICOA in its October 4 letter, ". . . is sufficient proof of preamendment status of the device. The other materials submitted could not be used as documentation."

The agency again dismissed SICOA's second protest by letter dated December 23, despite FDA's reversal of its initial determination that SICOA did not qualify for pre-amendment exemption. DPSC noted that under the terms of the solicitation, SICOA was required to resolve its Section 510(k) status 90 days prior to either the submission of its

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[3]Under FDA regulations, products that were in commercial use prior to May 28, 1976, are exempt from the FFDCA requirements.

initial offer or the original closing date, whichever comes first and the agency would not consider any new evidence of compliance with the pre-market notification requirements. On January 6, 1994, this Office received a protest from SICOA reasserting its arguments that it is entitled to receive the award as the lowest-priced, technically acceptable offeror.

Where, as here, a protest is first filed with the contracting agency, any subsequent protest to our Office must be filed within 10 working days of actual or constructive knowledge of initial adverse agency action on the protest. 4 C.F.R. § 21.2(a)(3) (1993); pH-Logistics, Inc., B-244162, May 29, 1991, 91-1 CPD ¶ 515. To be timely, therefore, SICOA's protest had to be filed within 10 working days of when it received the agency's September 23 letter, dismissing its protest since this constituted "initial adverse agency action."

SICOA's continuing attempts to persuade the agency to change its position by contacting the FDA, which resulted in further consideration by the FDA of its Section 510(k) status, did not suspend our timeliness requirements. Whether or not SICOA chose to continue pursuing the matter with the agency, its protest had to be filed in our Office within 10 days of the initial dismissal of its agency-level protest; once informed of initial adverse agency action, a protester may not delay filing a subsequent protest with our Office while it continues to pursue the matter with the agency. Techniventas, S.A.--Recon., B-240323.2, Oct. 19, 1990, 90-2 CPD ¶ 320. As SICOA did not file its protest within 10 working days of the agency's initial adverse action on September 23, its subsequent protest to our Office on January 6, 1994, is untimely.

The protest is dismissed.

Michael R. Golden
Assistant General Counsel