



**The Comptroller General  
of the United States**

Washington, D.C. 20548

## **Decision**

**Matter of:** Astro-Med, Inc.  
**File:** B-232633  
**Date:** December 22, 1988

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### **DIGEST**

1. Firm's noncompliance with solicitation provision calling for Food and Drug Administration approval is a matter of the firm's responsibility, and agency's rejection of bid as non-responsive instead of making responsibility determination (and referring any negative responsibility determination to the Small Business Administration for Certificate of Competency review) was improper.
2. Although Food and Drug Administration (FDA) determination as to firm's compliance with FDA registration requirement would not be subject to Small Business Administration (SBA) review, consideration of whether firm could meet the requirement by the time of performance is subject to SBA review.

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### **DECISION**

Astro-Med, Inc. protests the award of a contract to Cardiographics, Inc. under solicitation No. M1-114-88, issued by the Veterans Administration (VA) for electrocardiograph recording paper. Astro-Med contends that as apparent low bidder it was improperly denied the contract for failure to comply with a Food and Drug Administration (FDA) registration requirement. We sustain the protest.

The solicitation, issued on July 13, 1988, provided: "If the product(s) included in this solicitation is (are) considered medical devices by the U.S. Food and Drug Administration, bidders and/or subcontractors must comply with the Food, Drug, and Cosmetic Act, as amended, and regulations promulgated thereunder." The solicitation also specified that delivery was to be made within a maximum of 45 days after receipt of an order.

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After bid opening on August 15, Astro-Med was the apparent low bidder, but because the FDA advised the contracting officer that Astro-Med was not a registered supplier of the solicited item, as required under provisions of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360(c) (1982) (as implemented by 21 C.F.R. §§ 807.20-.39 (1988)), the VA declared Astro-Med nonresponsive. On September 7, award was made to Cardiographics, the next low bidder. On the same day, Astro-Med was notified of the nonresponsiveness of its bid and the award to Cardiographics. Astro-Med proceeded to register with the FDA, and on October 12 was approved as a supplier of the item.<sup>1/</sup> Performance of the contract has been stayed pending resolution of the protest.

Astro-Med contends that its bid was improperly rejected, and that it should have been given a chance to meet the FDA requirement prior to any award to a higher-priced bidder. Astro-Med notes in this regard that it began the process of registering with the FDA immediately upon notification of the deficiency, and that, in fact, registration was completed effective October 12, within the 45-day delivery period.

The VA concedes in its report that the FDA registration requirement pertains not to responsiveness, but to responsibility, since it concerns a bidder's ability to perform the contract rather than its agreement to the material solicitation terms and conditions. Nevertheless, as the protester was not registered with the FDA at the time of award, the VA argues that the rejection of Astro-Med as nonresponsive would have been proper. Although Astro-Med is a small business, and this matter was not referred to the Small Business Administration (SBA) under the Certificate of Competency (COC) procedures, the VA argues that referral would not have been necessary, since under Federal Acquisition Regulation (FAR) § 19.601(b), "the COC program does not extend to questions concerning regulatory requirements imposed and enforced by other federal agencies." The VA asserts that the FDA registration provision in the solicitation constituted such a requirement, and that Astro-Med's rejection thus did not have to be referred to the SBA.

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<sup>1/</sup> We have been advised by the FDA that registration involves only the completion and submission of a single form; issuance of a registration number is not contingent on any investigation of the firm or product.

We agree with the VA that the FDA registration requirement bears on the responsibility of the bidder, not the responsiveness of the bid. See Hewlett-Packard Co., Medical Products Group, B-216125.2, May 24, 1985, 85-1 CPD ¶ 597. We do not agree, however, that Astro-Med was not prejudiced by what occurred here since we believe referral to the SBA for a COC review is required.

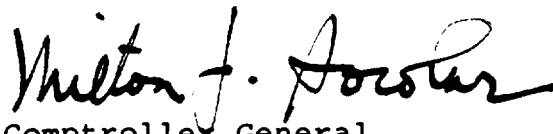
Generally, information bearing on bidder responsibility may be provided any time prior to award. Noslot Cleaning Services, Inc., B-228538, Jan. 21, 1988, 88-1 CPD ¶ 58. Moreover, actual compliance with certain requirements related to responsibility, such as for licenses and FDA requirements similar to the one here, need only be met by the start of performance. Chemical Compounding Corp., B-227333, June 15, 1987, 87-1 CPD ¶ 596; Impact Instrumentation, Inc., B-217291, Feb. 26, 1985, 85-1 CPD ¶ 240; Hewlett-Packard Co., Medical Products Group, B-216125.2, supra. All that is required in such cases is that the contracting officer, in determining the responsibility of the prospective awardee, find that the awardee has the ability to obtain the license or satisfy the regulatory requirement in time to perform as required. Impact Instrumentation, Inc., B-217291, supra. The agency's rejection of Astro-Med's bid outright as nonresponsive precluded a proper responsibility review concerning the FDA registration requirement. That is, the VA rejected the bid and eliminated Astro-Med from the competition without ever considering whether the firm would be able to satisfy the registration requirement by the time performance was to begin.

The VA's failure to consider Astro-Med's responsibility is significant for two reasons. First, we think it is reasonable to speculate that the agency may have found that Astro-Med could have met the FDA requirement in time to meet the 45-day delivery deadline; Astro-Med sought registration immediately upon being informed of its rejection on September 7, and was approved only 35 days later, on October 12. More importantly, even if there were reason to assume that the VA would have found Astro-Med nonresponsive, the VA's actions precluded referral to the SBA for a COC review. In this regard, we do not agree that FAR § 19.601(b) would have exempted referral in this case; the referral would not be for the purpose of allowing the SBA to determine compliance with the FDA registration requirement (which would be covered by the exemption), but to allow the SBA to consider whether Astro-Med could have met the requirement in time to perform. See Proper Mfg. Co., Inc., B-208035, Mar. 22, 1983, 83-1 CPD ¶ 279 (while compliance with FDA requirement was not itself subject to SBA review,

the contracting officer's decision as to likelihood of compliance by the time of performance should have been referred to the SBA). We therefore sustain the protest.

Although it ordinarily would follow from our decision that the matter of Astro-Med's responsibility now should be referred to the SBA, the firm's approval by the FDA on October 12 obviously rendered such a referral superfluous. Since Astro-Med was approved in time for performance and was otherwise in line for award as the apparent low bidder, we find Astro-Med is entitled to the award. Therefore, by separate letter to the Administrator, we are recommending that the VA terminate Cardiographics' contract for the convenience of the government and make award to Astro-Med, if otherwise appropriate. We also find Astro-Med entitled to recover the costs of filing and pursuing this protest. 4 C.F.R. § 21.6(a)(1) (1988); see Sanford and Sons Co., B-231607, Sept. 20, 1988, 88-2 CPD ¶ 266.

The protest is sustained.

*for*   
Comptroller General  
of the United States