



**The Comptroller General
of the United States**

Washington, D.C. 20548

Decision

Matter of: G&W Laboratories, Inc.

File: B-234543

Date: May 3, 1989

DIGEST

An awardee's compliance with a solicitation provision calling for the Food and Drug Administration's (FDA) review of medication's stability test data is a matter of responsibility and need only be met by the start of contract performance. Contentions that data submitted by the awardee to the FDA are invalid and that the testing of the product was not proper are not subject to review by the General Accounting Office.

DECISION

G&W Laboratories, Inc., protests the award of a contract to Able Laboratories under request for proposals (RFP) No. DLA120-88-R-1562 issued by the Defense Personnel Support Center (DPSC), Defense Logistics Agency (DLA), for hemorrhoidal suppositories. G&W contends that Able's product has not satisfied the RFP's 32-month expiration date requirement and that Able does not have available for review adequate stability data to support the expiration date claimed for its product. G&W also contends that Able does not sell the product to the general public and has previously violated Current Good Manufacturing Practices (CGMP) as promulgated by the Food and Drug Administration (FDA).

We dismiss the protest.

The RFP, issued on October 24, 1988, requested offers for an annual decentralized requirements contract with three ordering activities, including the DPSC, the Veterans Administration (now the Department of Veterans Affairs), and the Public Health Service for hemorrhoidal suppositories. The suppositories requested by the DPSC and by the Public Health Service were to have expiration dating of not less than 32 months, and the suppositories ordered by the

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Veterans Administration were to have expiration dating of not less than 18 months, at the time of delivery. The solicitation provided:

"Firms submitting offers to DPSC on Medical items having an expiration date requirement are cautioned that at the time of submission of offers they must have complete and adequate stability data to support their expiration date available for FDA review. Failure of a firm to have such stability data available for review when requested by FDA will make the firm's offer for the current solicitation subject to rejection."

The RFP closed on November 25 and six proposals were received. Able took no exception to the requirements in the solicitation and was evaluated as the lowest priced, technically acceptable offeror. The DPSC requested a pre-award survey from the Defense Contract Administrative Services Region (DCASR) and pre-award quality evaluations from the FDA. DCASR recommended award on all responsibility factors within its purview. On January 4, 1989, the FDA advised that Able had "the capability to furnish a product that is of appropriate quality and that meets the quality requirements of the solicitation." The contracting officer made an affirmative determination of responsibility and awarded the contract to Able on February 9.

G&W contends that the DPSC could not properly award this contract to Able because Able put its suppository manufacturing equipment on-line only 8 months before offers were due and therefore could not have conducted the required development and stability testing within FDA guidelines and still have a 32-month expiration date on its suppositories at time of delivery. G&W argues that Able does not sell this product to the public and that Able had been found in violation of CGMP in the areas of manufacturing and labeling controls in May 1986. These alleged violations included the lack of written procedures for stability testing and the lack of performance of stability testing at regularly scheduled intervals.

The DLA contends that the solicitation provision at issue does not require that a firm have the FDA review at the time of award, but only that it have stability data available for such a review. The DLA argues that this requirement pertains to the offeror's responsibility, not its offer's "responsiveness," since it concerns the firm's ability to perform the contract rather than its agreement to the material solicitation terms and conditions. Because the issue relates to Able's responsibility, the DLA contends

that it is only necessary that the FDA approve the stability data before performance of the contract and not before the award of the contract. In any event, the agency argues that Able had the data available for review prior to the February 9 award because the FDA issued a report on March 13 which indicates that the FDA reviewed stability testing data generated prior to February 1. Additionally, the technical portion of the DCASR's pre-award survey states that Able "will be able to supply stability data to support expiration dates for FDA review." Finally, in response to this protest, the FDA indicated that Able is in compliance with the CGMP for furnished pharmaceuticals as they apply to this product and that there is no CGMP requirement that the suppositories be sold to the general public by Able.

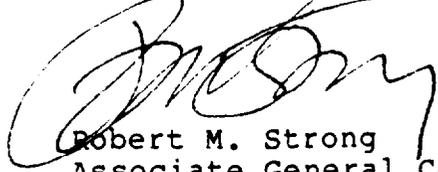
In its comments on the agency report, G&W argues that the data Able presented to the FDA was invalid, the assessment issued by the FDA was ambiguous and it is unclear if the FDA tested the two formulations of the suppositories required by the solicitation.

Able's offer did not take exception to the agency's requirements, including the expiration date. Here, by submitting its unqualified offer without taking exception to the stability testing provision, Able agreed to submit stability data for FDA review. It is our opinion that this type of requirement is clearly a matter of responsibility since it relates to the bidder's ability to provide the product required by the RFP. Midwest Contractor, Inc.; R.E. Scherrer, Inc., B-231101, B-231101.2, Aug. 8, 1988, 88-2 CPD ¶ 118. Generally, information bearing on an offeror's responsibility may be provided any time prior to award and need only be met by the start of performance. Astro-Med, Inc., B-232633, Dec. 22, 1988, 88-2 CPD ¶ 619. 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 satisfy the solicitation requirement in time to perform as required. Impact Instrumentation, Inc., B-217291, Feb. 26, 1985, 85-1 CPD ¶ 240. Such an affirmative determination of responsibility was made here. Our Office does not review an affirmative determination of responsibility unless there is a showing of possible fraud or bad faith or that definitive responsibility criteria were not applied. 4 C.F.R. § 21.3(m)(5) (1988); Everpure, Inc., B-231732, Sept. 13, 1988, 88-2 CPD ¶ 235. Neither of these exceptions has been alleged.

In any case, on March 13 the FDA stated that it had reviewed stability data generated by Able prior to February 1, 1989, that Able was in compliance with the CGMP and that the "FDA

would allow this product to be sold to the government or marketed commercially with a 33 month expiration date as of 2/1/89." Although G&W disputes the validity of Able's data and the testing of the two formulations of the suppositories required by the solicitation, these matters are within the jurisdiction of the FDA and thus not for review by our Office under our bid protest function. Impact Instrumentation, Inc., B-217291, supra; Advanced Telecommunications Corp., B-233274, Feb. 24, 1989, 89-1 CPD ¶ ____.

The protest is dismissed.



Robert M. Strong
Associate General Counsel