DECISION

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

u1080

FILE: B-185765 DATE: July 6, 1976

MATTER OF: Chaston Medical and Surgical Products, Inc.

98343

DIGEST:

Drug stability data submitted by offeror to comply with solicitation requirement and found to be inadequate by preaward survey, which finding was affirmed by Food and Drug Administration, presents reasonable basis for finding offeror nonresponsible.

The Defense Personnel Support Center (DPSC), Philadelphia, Pennsylvania, issued solicitation No. DSA120-76-R-0615 for an estimated quantity of 9,552 boxes of Povidone iodine solution, USP, 10 percent, 1/2 fluid ounce, national stock number 6505-00-914-3593, on October 10, 1975. This procurement was to be negotiated with The Purdue Frederick Company (Purdue) under authority of 10 U.S.C. § 2304(a)(7) (1970), as DPSC believed that Purdue was the only potential offeror.

However, prior to the closing date, DPSC received an offer from Chaston Medical and Surgical Products, Inc. (Chaston). During the time required to conduct a preaward survey on Chaston and its subcontractors, the Defense Medical Material Board informed the DPSC that the essential characteristics of the drug had been revised to include a requirement that any supplier of the drug had to possess a New Drug Application (NDA).

Based on this information, DPSC canceled solicitation No. -0615 and issued request for proposals (RFP) No. DSA120-76-R-0942 which included the requirement for a NDA. Chaston submitted the low offer under the new solicitation. However, award of the contract was made to Purdue, the second low offeror, since the contracting officer determined that Chaston was not a responsible offeror. Chaston has protested this determination of nonresponsibility to our Office in a timely manner.

One of the bases upon which the contracting officer found Chaston to be nonresponsible was its lack of adequate stability data to meet a 36-month shelf life or expiration date requirement contained in the RFP.

Initially, Chaston argues that the RFP did not require that the item have a 36-month shelf life. The RFP stated that "Potency-not less than 36 months" was to be added to the description of the item in the identification block of the specification data sheet. Chaston contends that the item was to have an expected 3-year potency and be so labeled and that the above-quoted clause cannot be read to require a 3-year shelf life. The RFP did not contain a specific requirement for either a 3-year shelf life or expiration date except for a reference in the United States Pharmacopeia (USP). The USP is the official compendium of pharmaceutical compounds used by the pharmaceutical industry and the RFP provided that the item being procured was to be in accordance with the tests, standards and requirements of the latest revision. The USP, 19th Revision, July 1975, provides, at page 698, that:

> "Expiration dating is a valuable quality attribute and is required for all Pharmacopeial dosage forms. The expiration date preferably should be accompanied by specific storage conditions as provided in the Pharmacopeia for this purpose (see page 8). Adequate stability data acquired by the manufacturer should be available to support the expiration date and storage specified."

DPSC contends that the 36-month potency requirement was the same as an expiration date of 3 years or a shelf life of 3 years. While there is disagreement among the parties as to the exact technical meanings of potency, expiration date and shelf life, we have been advised by the Food and Drug Administration (FDA) that all three are synonomous. Whatever term is used, we believe all involve the stability of the drug over a period of time and that an offeror had to prove its drug stable over the specified period of time (36 months).

When Chaston was advised that it had been found nonresponsible by a letter dated January 9, 1976, from the contracting officer, the following two findings of the preaward survey team were recited:

> "4. A review of stability data disclosed that the firm has not generated any data for stability upon which the prime contractor may draw. The prime offeror would not meet the required expiration dating of 36 months. Hydron Labs [Chaston's subcontractor] has been manufacturing the item for approximately 12 months.
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> "5. The immediate container (squeeze-type) has not been accepted by the Food and Drug Administration. The packager has no stability data for the item."

Following receipt of this letter, Chaston submitted its stability data to DPSC which, in turn, forwarded the data to the FDA for its review. In a letter dated March 3, 1976, the Medical Products Quality Assurance Staff, FDA, advised DPSC as follows:

> "The data does not support the Hydro Med conclusion in their February 13, 1976, letter to us that a three year expiration date is justified for Povidone. What can be extracted is that the firm has made one batch that appears to be stable for fourteen days at elevated temperature, without any assurance that heat is a trigger of degradation. This data is supplemented with three months stability at ambient temperature. The data provided us does not give enough information to make a valid judgment on the stability of the Povidone-Iodine Solution. * * *"

Based on this information, the contracting officer affirmed his prior determination of Chaston's nonresponsibility.

In view of the foregoing, we believe there was a requirement in the RFP for the Povidone iodine to have a proven stability of 36 months, irrespective of the term used (potency, expiration date or shelf life), and that Chaston failed to comply with this requirement as evidenced by the FDA letter of March 3, 1976.

This Office has consistently held that it is the duty of the contracting officer to determine the responsibility of a prospective contractor. In making the determination, the contracting officer is vested with a considerable degree of discretion. Our Office will not substitute its judgment in such cases and will uphold the contracting officer's determination of nonresponsibility unless it is shown to be inconsistent with the information before him or to have been made in bad faith. Solar Laboratories, Inc., B-179731, February 25, 1974, 74-1 CPD 99; 51 Comp. Gen. 703, 709 (1972).

While Chaston argues that its stability data is adequate to prove a potency of not less than 36 months, we do not find that the opinion of FDA has been refuted and believe the contracting officer, based on this information, had a reasonable basis for his determination of nonresponsibility and the protest is denied.

The above holding renders the other issues advanced by the protester academic and will not be considered.

R. F. Keller

Deputy Comptroller General
of the United States