DECISION

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

FILE: B-189420 DATE: July 24, 1978

MATTER OF: Noble Pine Products Co.

DIGEST:

Contracting officer's determination of non-responsibility, based upon offeror's failure to receive FDA approval, was reasonable, even though FDA was unable to evaluate offeror's foreign supplier, where negotiations had proceeded for six months and new supplies were urgently needed. Burden is on offeror to obtain such approval either before or within reasonable time after submitting proposal.

Noble Pine Products Co. protests the award of two contracts by the Defense Logistics Agency's Defense Personnel Support Center (DPSC), Philadelphia, Pennsylvania, resulting from three solicitations for medicated shampoo.

For each of the three solicitations, offers were received from only two companies: Westwood Pharmaceuticals and Noble Pine Products. In each case Noble Pine submitted the lower offer. Noble Pine indicated that it intended merely to repackage the product itself and to subcontract the manufacturing operations to Squire Laboratories and to obtain its raw materials from a New Jersey distributor.

The DPSC issued solicitation No. DLA120-77-R-1177 (1177) on March 22, 1977, and closed it on April 13, 1977. On April 15, 1977, DPSC requested two preaward surveys be performed on Noble Pine. The first, conducted by the Defense Contract Administration Services (DCAS), attempted to evaluate the firm's status as a manufacturer under the Walsh-Healey Act, 41 U.S.C. § 35 (1970); the second, conducted by the Food and Drug Administration (FDA) was to evaluate Noble Pine's

compliance with quality standards and current good manufacturing practices (CGMP), 21 C.F.R. § 210.3. FDA approval, though not required specifically by the solicitation, is required by the Food, Drug and Cosmetic Act, 21 U.S.C. § 321 et seq (1970).

As a result of the preaward surveys, Noble Pine was not approved as a manufacturer under the Walsh-Healey Act or as a repackager of drugs by the FDA. Upon learning that it did not qualify as a manufacturer, Noble Pine protested solicitation 1177 to this Office on June 23, 1977. A supplemental report by DCAS found Noble Pine to be eligible as a manufacturer. The contracting officer, however, apparently disagreed and informed Noble Pine on August 2, 1977 that it was not eligible for award because it was not a manufacturer under the Walsh-Healey Act. Noble Pine protested this finding to the contracting officer on August 17, 1977 with regard to solicitation 1177 and solicitation DLA120-77-R-1729 which had been issued on June 1, 1977 and closed on June 23, 1977. The contracting officer then reconsidered his earlier finding and on September 1, 1977 found Noble Pine eligible as a manufacturer. Nevertheless, because it had not been approved as a repackager by the FDA, the firm was not qualified for award.

The FDA was required not only to approve Noble Pine as a repackager, but to approve the source of all active ingredients in the shampoo. On August 13, 1977, the FDA approved the supplier of salicylic acid and reported that it was in the process of evaluating Noble Pine's West German supplier of sulphur. FDA also attempted to identify and evaluate Noble Pine's source of coal tar extract. It should be noted that supplies of the needed item were so low that on October 31, 1977, an emergency procurement was made.

During the next two months, negotiations with Noble Pine proceeded in an effort to obtain FDA approval of its repackaging operations and its suppliers. On November 4, 1977, DPSC suggested to Noble Pine that it find a substitute supplier of coal tar extract because the

FDA did not believe that its supplier manufactured pharmaceutical grade coal tar. Noble Pine refused, arguing that its supplier was acceptable. Finally, on November 30, 1977, FDA informed DPSC that it had received the necessary information from Noble Pine and was in the process of reevaluating its status as a repackager and evaluating its supplier of coal tar extract. The FDA indicated, however, that it was unable to evaluate Noble Pine's sulphur supplier because that firm refused to permit an inspection of its facilities.

During the pendency of the preceding negotiations, the remaining solicitation, DLA120-77-R-2063, was issued on July 18, 1977 and closed on August 9, 1977. Because all of Noble Pine's suppliers were identical, the same deficiencies existed with this solicitation as had with solicitation 1177 and 1729. Noble Pine states, however, that since the resolution of its GAO protest regarding solicitation 1177 would apply to solicitations 1729 and 2063 as well, it did not protest these solicitations while negotiations were being conducted.

On December 19, 1977, the contracting officer decided to reject the offers of Noble Pine on solicitations 1729 and 2063 because new supplies of the product were urgently needed and Noble Pine was not in conformance with FDA regulations and thus not qualified for award. On January 3, 1978 award was made to Westwood Pharmaceuticals. Noble Pine was approved by the FDA as a repackager on the same day. Noble Pine was informed that its offers had been rejected because the FDA was unable to evaluate its supplier of sulphur in solicitations 1729 and 2063 and was unable to approve a pharmaceutical grade of coal tar extract in solicitation 2063. Award was not made on solicitation 1177 at this time however. The deficiencies in that offer were ultimately resolved when Noble Pine identified a substitute sulphur supplier and received FDA approval of its supplier of coal tar extract. On March 23, 1978, Noble Pine withdrew its protest on solicitation 1177; it was awarded the contract several weeks later.

Noble Pine argues that it believed the contracts on solicitations 2729 and 2063 were in the process of being awarded to it when it was informed of its rejection. It claims its suppliers were acceptable and it was attempting to obtain FDA approval. DPSC, however, states that Noble Pine was not a responsible offeror until FDA approval was received and thus we should dismiss Noble Pine's protest. The agency relies upon several recent decisions of our office which have held that the FDA has the authority to determine compliance with its regulations, and that our office will not review a negative determination of responsibility based upon noncompliance with FDA requirements. Lemmon Pharmacal Co., B-188982, June 1, 1977, 77-1 CPD 381; Lemmon Pharmacal Co., B-189048, July 25,1977, 77-2 CPD 47; Carlisle Laboratories Inc., B-186957, B-187059, B-187131, Feb. 22, 1977, 77-1 CPD 124.

Although we do not disagree with those decisions, a distinction should be noted. In both Lemmon and Carlisle, the contracting officer relied upon the FDA's conclusions that the protester was not in compliance with its regulations in finding the firms nonresponsible. We held that since the FDA has the authority to determine compliance with its regulations, we will no longer review a determination of nonresponsibility based upon its conclusions. In this case, however, the FDA made no evaluation of Noble Pine's suppliers. Rather, it was attempting to evaluate them at the time awards were made. Although the FDA had reached a negative conclusion with regard to Noble Pine's status as a repackager, it reversed this conclusion on January 3, 1978. The contracting officer's determination of nonresponsibility, therefore, was not based upon the FDA findings as it was in the Lemmon and Carlisle cases.

This Office has consistently held that the contracting officer's determination of a contractor's nonresponsibility will be upheld as long as no bad

faith is shown and there is a reasonable basis for the determination. 49 Comp. Gen. 553 (1970). See Lemmon Pharmacal Co., B-189048 supra. In this case, negotiations with Noble Pine had proceeded for approximately six months, during which time several deficiencies were resolved. A major deficiency, Noble Pine's status as a repackager of drugs, was not resolved until January 3, 1978, the date the contract was awarded to Westwood Pharmaceuticals. By this time, the contracting officer had already determined that award must be made because supplies of the needed item were critically short. Under these circumstances, the decision of the contracting officer to reject Noble Pine's offer was reasonable. Moreover, the fact that the contracting officer waited six months before making award, combined with the fact that he held up award on protested solicitation 1177 until FDA approval was obtained, indicate his good faith in assisting Noble Pine to qualify for award.

Noble Pine points out that with respect to solicitation 1729, the only reason given for its rejection was the lack of FDA approval of its sulphur supplier. Although DPSC knew for several months that the FDA was attempting to evaluate the supplier, it failed to notify Noble Pine of this deficiency and thus did not afford it a reasonable opportunity to correct the deficiency as required by the Armed Services Procurement Regulation (ASPR) 3-805.3(a). The cited regulation concerns the conduct of discussions with offerors included in the competitive range and therefore does not strictly apply to the matter of obtaining FDA approval as a condition of award. In any event, we believe that the protester should be deemed to have known that its proposed supplier would not permit an FDA inspection of its plant.

With regard to solicitation 2063, Noble Pine's argument is even less convincing. Noble Pine had been notified on November 4, 1977 that the FDA was unable to evaluate its supplier of coal tar extract but it failed to change suppliers or to provide the information

necessary to obtain FDA approval. Thus, in addition to the reasons discussed above, Noble Pine's failure to correct the deficiency justified the conclusion that it was not a responsible offeror.

We note that at the time Noble Pine responded to each of the three solicitations, its proposed suppliers lacked FDA approval. In a procurement requiring such approval as a condition precedent to award, we believe the burden should be on the offeror to obtain it, either before or within a reasonable time after submitting its proposal. A procuring agency is not obliged to unduly delay while the offeror or its proposed suppliers attempt to qualify for award.

Accordingly, the protest is denied.

Deputy Comptroller General
of the United States