## DOCUMENT RESUME

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[Protest against Award of Purchase Order]. B-189048. Jugy 25, 1977. 2 pp.

Decision re: Lemmon Pharmacal Co.; by Robert F. Keller, Deputy Comptroller General.

Issue Area: Federal Procurement of Goods and Services (1900). Contact: Office of the General Counsel: Procurement Law I. Budget Function: General Government: Other General Government (806).

Organization Concerned: Department of Health, Education, and Welfare; "ood and Drug Administration.

Authority: Fe Bral Pood, Brug, and Cosmetic Act (21 U.S.C. 301 ot seq.). B-186987 (1977). B-187059 (1977). B-187131 (1977). B-179731 (1975). 51 Comp. Gen. 703. 51 Comp. Gen. 709.

The protester objected to rejection of its bid on the basis that it was not a responsible bidder. The agency's finding, upon which the determination of nonresponsibility was based, that the bidder's plant did not conferm to current good manufacturing practices was not reviewed. The fact that after the award the agency made a determination that the bidder was in compliance with such practices did not affect the earlier determination of nonresponsibility based on the determination of noncompliance. (Author/SC)

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THE COMPTROLLER GENERAL DF THE United States Washington, D.C. 20548

FILE: 3-189048

DATE: July 25, 1977

MATTER OF:

Lemmon Pharmacal Company

## DIGEST:

0301

- 1. Food and Drug Administration finding, .pon which determination of nonresponsibility is based, that bidder's plant did not conform to current good manufacturing practices will not be reviewed.
- Fact that after award Food and Drug Administration made determination that bidder was in compliance with current good manufacturing practices does not affect determination of nonresponsibility wade upon Food and Drug Administration determination at time of award that bidder was not in compliance.

Lemmon Pharmacal Company (Lemmon) has protested the award of a purchase order by the Department of Health, Education, and Welfare (HEW) under request for quotation (BFQ) No. DA12-76-0397.

Two offers were received in response to the RFQ. On March 16, 1977, HEW advised Lemmon that, based on a survey of its plant by the Food and Drug Administration (FDA), it was not a responsible bidder. The FDA found Lemmon not to be in conformity with current good manufacturing practices under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301, et seq. (1970)). On March 21, 1977, Lemmon protested the rejection to HEW and asserted that as a result of a reinspection of its facilities it had reason to believe that the FDA had or would find it to be in compliance with current good manufacturing practice. On March 1977, the contracting officer called FDA to inquire whether the provides finding of nonconformance had been reversed. FDA advised that as of March 24 the finding of nonconformance had not been changed.

In <u>Carlisle Laboratories</u>, Inc., B-186987, B-187059, E-187131, February 22, 1977, 77-1 CPD 124, we decided we will no longer review protests involving the rejection of a bid because of nonconformance with a requirement within the cognizance of FDA. Since FDA determined that Lemmon was not in compliance with the "current good manufacturing practice" requirement of the act, the protest is denied in this regard.

## B-180048

Lemmon also objects to the time lag by FOA between the reinspection and reversal of the nonconformance finding (which occurred after award of the purchase order). While the delay is unfortunate, it does not afford a basis for disturbing the award. Į.

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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 degrae 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. <u>Solar Laboratories, Inc.</u>, B-179731, February 25, 1974, 74-1 CPD 99; 51 Comp. Gen. 703, 709 (1972).

The fact that, subsequent to award of the purchase order, Lemmon was determined to be in compliance with current good manufacturing practices does not affect the responsibility determination made at the time of award. The propriety of the nonresponsibility determination is tested against the information available prior to the award. When the contracting officer determined Lemmon not to be a responsible offeror, the FDA had not reversed its prior finding of nonconformance. Lemmon's assurances that the nonconformity finding could be subsequently reversed cannot be taken into account and do not contradict the bases of the determination. Consequently, the determination of Lemmon's lack of responsibility will not be disturbed or questioned further.

For the reasons set forth above, the protest of Lemmon is denied.

Deputy Comptroller Genersi of the Uni 2d States