

DOCUMENT RESUME

02401 - [A1602582]

[Protest to Finding of Nonresponsibility]. B-188982. June 1, 1977. 2 pp.

Decision re: Lemmon Pharmacal Co.; by Paul G. Dembling, General Counsel.

Issue Area: Federal Procurement of Goods and Services (1900).

Contact: Office of the General Counsel: Procurement Law II.

Budget Function: National Defense: Department of Defense - Procurement & Contracts (058).

Organization Concerned: Defense Logistics Agency; CIBA Pharmaceutical Corp.; Food and Drug Administration.

Authority: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.). B-186987 (1977). B-187059 (1977). B-187131 (1977). 4 C.F.R. 20. Bid Protest Procedures, sec. 20.2(1).

Lemmon Pharmacal Company protested the award of a contract to another company. The Food and Drug Administration found that Lemmon's plant did not conform to current good manufacturing practices. GAO will not review a bid rejection based on an FDA determination of nonresponsibility. As the protest was untimely, it was not for consideration on the merits. (QM)

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**DECISION**



L. Roylance  
Proc. I

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

**FILE:** B-188982

**DATE:** June 1, 1977

**MATTER OF:** Lemmon Pharmacal Company

**DIGEST:**

1. Food and Drug Administration finding, upon which determination of nonresponsibility is based, that bidder's plant did not conform to current good manufacturing practices will not be reviewed by this Office.
2. Protest not filed within 10 working days from date of initial adverse agency action (receipt of denial of protest) is untimely and not for consideration on merits.

Lemmon Pharmacal Company (Lemmon) has protested the award of a contract to Ciba Pharmaceutical Company by the Defense Logistics Agency (DLA) under invitation for bids No. DSA120-76-B-3042.

On January 11, 1977, DLA advised Lemmon by letter that, based on a survey of its plant by the Food and Drug Administration (FDA), Lemmon 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. § 321, et. seq. (1970)). Lemmon filed a protest with DLA on January 12, 1977.

DLA awarded the contract on January 14, 1977, and advised Lemmon that a detailed reply to the protest would be provided upon receipt of additional information from the FDA. By letter dated March 16, 1977, DLA denied Lemmon's protest and asserted that the FDA evaluation was correct.

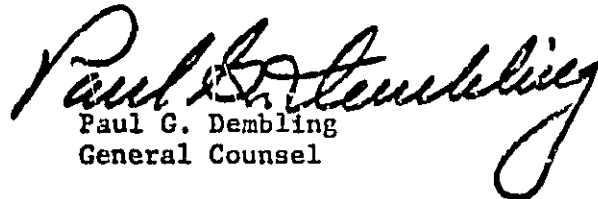
In Carlisle Laboratories, Inc., B-186987, B-187059, B-187131, February 22, 1977, 77-1 CPD 124, we decided we will no longer review protests involving the rejection of a bid because of nonconformance with a requirement within the cognizance of FDA. Since the FDA determined that Lemmon was not in compliance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

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While Lemmon raises certain issues regarding the propriety of the nonresponsibility determination which may be subject to review by this Office, we need not decide those issues since, in any event, the protest was untimely filed.

An information copy of Lemmon's protest of January 12, 1977, to DLA was sent to our Office. By letter dated January 21, 1977, we advised Lemmon that in order for the communication to be regarded as a protest, Lemmon must specifically request a ruling by the Comptroller General. A copy of our Bid Protest Procedures (4 C.F.R. part 20 (1976)) was provided to Lemmon. Additionally, we pointed out that section 20.2(a) of our Bid Protest Procedures provides that when a protest has been filed initially with the contracting agency, any subsequent protest to this Office must be filed no later than 10 working days from formal notification of or actual or constructive knowledge of initial adverse agency action.

The detailed reasons for determining Lemmon not to be a responsible bidder were set forth in a March 16, 1977, letter from the contracting officer to Lemmon. The protest to our Office was not filed (received) until May 2, 1977. Therefore, the protest of Lemmon is untimely and not for consideration on the merits.

  
Paul G. Dembling  
General Counsel