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L. Kuykendall
Proc I

DECISION

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

FILE: B-186987, B-187059, B-187131 DATE: February 22, 1977

MATTER OF: Carlisle Laboratories, Inc.

DIGEST:

Food and Drug Administration (FDA) finding that drug stability data did not support prescribed expiration dates contained in solicitation is not subject to review by this Office.

Carlisle Laboratories, Inc. (Carlisle), protests against the awards of contracts by the Defense Personnel Support Center (DPSC), Defense Supply Agency (DSA), under requests for proposals (RFP) Nos. DSA120-76-R-1829; -1876; -1880. Each RFP requested offers for differing amounts of various types of drugs and required that the items offered have a potency for a prescribed period of time. The Food and Drug Administration (FDA), based upon information provided by Carlisle, determined that Carlisle's items did not meet the prescribed potency requirements. Relying on FDA's findings, the contracting officer determined that Carlisle was not a responsible offeror under the RFP's. Carlisle protested the determination. The contracting officer awarded the contracts to firms other than Carlisle.

The record before this Office reflects that the contracting officer requested the FDA to perform surveys on Carlisle and the other offerors under the respective RFP's. FDA recommended that Carlisle not be awarded a contract for the drugs because of inadequate stability data to meet the expiration date requirements contained in the RFP's. While Carlisle had done accelerated studies to substantiate the required expiration datings, FDA will not approve accelerated studies to support expiration dates for more than 1 year. The expiration dates for the respective RFP's were 18 and 24 months.

Subsequent to award, FDA recommended Carlisle for award under another RFP because of adequate stability data to support the required expiration dating period for the same product called for under one of the above RFP's. Carlisle contends that the stability data made available to the FDA, at the time of the survey under the above RFP's, was adequate to support the respective expiration dating periods. Essentially, Carlisle contends that FDA's conclusions were erroneous and that, based upon its own interpretation of the data, the expiration dates had been established.

Section 331 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321, et seq. (1970)) contains certain prohibitions concerning adulterated drugs. Section 351 of the act provides that a drug shall be deemed adulterated if, inter alia, the "methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess * * *." In implementation of the "current good manufacturing practice" requirement, 21 C.F.R. § 211 (1976) provides that drugs known to deteriorate bear an expiration date supported by readily available data from stability studies. Noncompliance with this requirement results in a finding that the drug is adulterated within the meaning of the act. The Food and Drug Administration has the responsibility and authority for implementing and enforcing the act.

In view thereof, we will no longer review protests involving the rejection of a bid for nonconformance with a requirement which is within the cognizance of FDA and, therefore, the subject protest is denied.

Acting Comptroller General
of the United States