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Comptroller General
of the United States

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Washington, D.C. 20548

Decision

Matter of: Roche Diagnostic Systems, Inc.

File: B-255578.2

Date: June 22, 1994

Steven S. Diamond, Esq., and Walter F. Zenner, Esq., Arnold & Porter, for the protester.
Michael T. Janik, Esq., and Mark J. Meagher, Esq., McKenna & Cuneo, for Immunalysis Corporation, an interested party.
John R. Osing, Jr., Esq., Department of the Navy, for the agency.
Richard P. Burkard, Esq., and John Van Schaik, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

Protest that awardee's product did not comply with Food and Drug Administration (FDA) approval requirement contained in solicitation is denied where FDA, after reviewing allegation independently, has advised our Office that the awardee's product, in fact, complies with the requirement.

DECISION

Roche Diagnostic Systems, Inc. protests the award of a contract to Immunalysis Corporation under request for proposals (RFP) No. N62645-93-R-0025, issued by the Department of the Navy for drug testing kits. Roche contends that the awardee's kit is not approved by the Food and Drug Administration (FDA) as required by the RFP.

We deny the protest.

The RFP provided that the testing kits to be acquired are "medical devices and must have clearance from the [FDA] to be marketed." It stated further that "[a]ny changes to the FDA cleared kit shall be covered by resubmission of a 510(k)," the FDA application for product approval.[1] The Navy states that prior to awarding the contract to Immunalysis, it verified with FDA that the firm's kit had FDA's approval.

[1]This terminology is based upon the relevant section of the Federal Food, Drug, and Cosmetics Act, which is codified at 21 U.S.C. § 360(k) (1988).

Roche's protest is based on the fact that, after receiving FDA approval, Immunalysis modified its kit in order to correct a solubility problem which became apparent under a previous contract.[2] Roche contends that since the modification to the product "significantly affected" the effectiveness of the kit, FDA regulations require that the Immunalysis kit receive new 510(k) approval. 21 C.F.R. § 807.81(a)(3)(i) (1994). Without such approval, Roche argues, Immunalysis's test kit failed to satisfy a mandatory RFP requirement for FDA approval and was ineligible for award. Both the Navy and the awardee contend that the modification to the test kit was not the type which triggered the requirement for resubmission of a 510(k).

We requested the views of the FDA concerning this protest allegation. After reviewing the relevant facts and the positions of the parties, the FDA provided our Office with a written response concluding that the change to the Immunalysis kit did not require the submission of a new 510(k). FDA's response explained the basis for its conclusion and was provided to the parties; Roche declined our invitation to comment on the FDA response. Based on the FDA response, we conclude that the Immunalysis kit had the necessary approval from the FDA and there was no need to submit a new 510(k). To the extent that the language in the RFP required FDA review and approval of "any changes" to proposed test kits (i.e., whether or not the change had any material effect on the kits), the protester has not shown, nor do we see, how under the circumstances, the protester was prejudiced by Immunalysis's decision not to submit a new 510(k).

The protester also contends that the Immunalysis kit failed to meet an RFP requirement concerning solubility of compounds in the kit. This argument is based on a problem with the Immunalysis kit which the agency found to have been corrected. Other than simply questioning the agency's finding, Roche has presented no evidence that the agency's evaluation in this regard is unreasonable. The protester's disagreement with the agency's conclusion is not itself sufficient to establish that the evaluation was improper.

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[2]Immunalysis considers the modification to involve proprietary information. We therefore do not describe the modification here.

See ASR Mgmt. & Technical Servs., B-252611, July 15, 1993, 93-2 CPD ¶ 22. Thus, in our view, the agency reasonably determined the Immunalysis proposal to be acceptable.

The protest is denied.

Robert P. Murphy
Acting General Counsel