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Comptroller General
of the United States

Washington, D.C. 20548

Decision

Matter of: Lederle-Praxis Biologicals

File: B-255996; B-255996.2

Date: April 25, 1994

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Michael Colvin, Department of Health & Human Services, for the agency.
Paula A. Williams, Esq., and Michael R. Golden, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

1. Protest that awardee's proposal failed to comply with solicitation licensing requirement which constitutes a definitive responsibility criterion is denied where the agency had sufficient evidence to reasonably conclude that the awardee had obtained the required license and to determine that this information satisfied the solicitation requirement.

2. Allegations that awardee was given an unfair competitive advantage are dismissed where the protester does not provide a sufficient legal or factual basis to conclude that the agency gave the awardee any such advantages.

DECISION

Lederle-Praxis Biologicals protests the award of a contract to Connaught Laboratories, Inc. by the Department of Health & Human Services, Centers for Disease Control and Prevention (CDC), under request for proposals (RFP) No. 93-133(N), to obtain an indefinite quantity of a pediatric vaccine. Lederle alleges that Connaught's product is noncompliant with material requirements of the solicitation and that CDC relaxed its requirements in order to make award to Connaught.

We deny the protest in part and dismiss it in part.

The RFP, issued on June 14, 1993, contemplated award of a firm, fixed-price requirements contract under which the government would issue delivery orders to obtain a combination diphtheria and tetanus toxoid with whole cell pertussis vaccine combined with hemophilus influenza type B vaccine (DTP/HiB).[1] The solicitation stated that a vaccine combination may be used instead of a single shot preparation of DTP and HiB. Section B of the RFP contained the schedule of contract line items for which fixed prices were sought for either 10-dose or 15-dose size vials for a total estimated quantity of 3,000,000 doses. No separate technical proposals were required.

With regard to contract award, section M of the solicitation, "EVALUATION FACTORS FOR AWARD," contains the following clause at issue in these protests:

> "M.1.a. The low responsible offeror must possess a current FDA [Food and Drug Administration] license for the proposed product and operate in accordance with the Current Good Manufacturing Regulations. IN ORDER TO BE CONSIDERED FOR AWARD, OFFEROR MUST SUBMIT EVIDENCE OF A CURRENT FDA LICENSE."

This language is essentially repeated in section H of the RFP, "SPECIAL CONTRACT REQUIREMENTS," which states in relevant part:

> "H.3 PRODUCT LICENSURE
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> "The vaccines produced and delivered under this contract shall be manufactured under a current establishment and product license issued by the [FDA] as indicated below:
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> "License Numbers: _____"

Only Lederle and Connaught submitted initial proposals by the July 30 extended closing date. Lederle's proposal offered to provide a pre-mixed vaccine marketed under the

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[1]The combination of these two separate pediatric vaccines, DTP and HiB, will provide immunization against the childhood diseases--diphtheria, tetanus, and pertussis (whooping cough) and hemophilus influenza type B (the leading cause of meningitis)--using four injections instead of the eight injections which are currently needed. Use of the combination vaccine may increase compliance with vaccination programs.

tradename TETRAMUNE[2] in a 10-dose size vial, and the protester included a copy of its FDA license for this product in its proposal. Connaught, on the other hand, submitted a proposal to provide a combination DTP/HiB vaccine in a 10-dose package consisting of one 10-dose size vial of DTP and 10 1-dose size vial of HiB vaccine which would be reconstituted prior to injection by the user, even though it had no current FDA license for this product. In its proposal, Connaught indicated that it had a product license application pending for this combined DTP/HiB vaccine. Discussions were held with both offerors; thereafter, best and final offers (BAFO) were received and evaluated. Lederle's BAFO price was $15.38 per dose while Connaught proposed a BAFO price of $9.63 per dose. On November 18, Connaught furnished information to the contracting officer to demonstrate that it had obtained the required FDA approval for its combination vaccine and the agency subsequently made award to that firm as the responsible offeror submitting the low-priced offer.

Lederle protests that the award to Connaught was improper on the grounds that Connaught did not possess a current FDA license for a combined DTP/HiB vaccine and was not operating in accordance with the current FDA manufacturing regulations as of the July 30 date for submission of initial proposals. According to the protester, the language in section M.1.a quoted above, unequivocally made compliance with the FDA license requirement a prerequisite to submitting an initial proposal.

We find no merit to this argument. Solicitation requirements, such as the licensing provision quoted above, which require a successful contractor to have a specific license, are definitive responsibility criteria. Definitive responsibility criteria are specific and objective standards established by an agency for a particular procurement to measure an offeror's ability to perform the contract; failure to meet a definitive responsibility criterion renders a firm nonresponsible and ineligible for contract award. Federal Acquisition Regulation (FAR) § 9.104-2; Stocker & Yale, Inc., B-238251, May 16, 1990, 90-1 CPD ¶ 475. Contrary to the protester's position, there is no language in section M which required that the license be furnished with the initial offer. Rather, the provision is silent as to the precise time when the license is required. It states only that the license is required for a firm "to be considered for award." While the provision states that the low responsible offeror must have a license, the

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[2]On March 30, 1993, the FDA issued a license for TETRAMUNE, a combination DTP/HiB vaccine manufactured by Lederle. This is the first DTP/HiB vaccine to be licensed by the FDA.

responsibility of an offeror is determined after submission of offers and prior to award. Thus, we conclude that the license requirement is a precondition to an affirmative determination of responsibility and the receipt of an award, and that Lederle's interpretation of that provision (i.e., that a prospective offeror had to have an FDA license prior to submission of its proposal) is simply incorrect.

Moreover, since at the time the solicitation was issued, Lederle was the only firm that had an existing FDA license for a combination vaccine, the protester's argument is no more than a request by Lederle to read the solicitation more, not less, restrictively, and thereby minimize competition. We will not read solicitation provisions in a manner which restricts competition unless it is clear from the solicitation that such a restrictive interpretation was intended. See Impact Instrumentation, Inc., B-250968.2, Mar. 17, 1993, 93-1 CPD ¶ 241.

Regarding Connaught's compliance with the licensing requirement, the record shows that the agency properly concluded that the firm met the requirement prior to receiving the award. As stated previously, in a letter dated November 18, the FDA granted Connaught's request to amend its existing DTP and HiB licenses to allow the firm to combine these two vaccines.[3] Since the November 18 letter from the FDA evidenced compliance with the RFP's licensing requirement and nothing on the face of the information calls its verity into question, see generally Apex Envtl., Inc., B-241750, Feb. 25, 1991, 91-1 CPD ¶ 209, the contracting officer determined that Connaught was capable of successful performance and made award to that firm on November 30, 1993. Under these circumstances, we think the agency reasonably determined that Connaught furnished adequate evidence of compliance with the licensing requirement. Our Office has no basis to question this determination or the subsequent award to that firm. See Prime Mortgage Corp., 69 Comp. Gen. 618 (1990), 90-2 CPD ¶ 48; T. Warehouse Corp., B-248951, Oct. 9, 1992, 92-2 CPD ¶ 235.

Lederle also argues that Connaught's product is not "DTP combined with the HiB vaccine," but, rather, is merely two distinct vaccines which may or may not be combined prior to use; it thus fails to meet the solicitation requirement for

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[3]As previously stated, the Connaught vaccine is packaged as a 10-dose pack consisting of a 10-dose vial of DTP and 10 single dose vials of HiB vaccine. Prior to injection by the user, the DTP would be withdrawn in 0.5 ml amounts and injected into a single dose vial of HiB to combine the two vaccines; the vaccine is then ready for delivery to the patient by a single injection.

a combination DTP/HiB vaccine. In negotiated procurements, any proposal which fails to conform to the material terms and conditions of the solicitation should be considered unacceptable and may not form the basis for award. See National Medical Staffing, Inc.; PRS Consultants, Inc., 69 Comp. Gen. 500 (1990), 90-1 CPD ¶ 530.

The record does not support Lederle's allegation that Connaught submitted a noncompliant offer since there is no question that Connaught's product is a combination DTP/HiB vaccine. The record shows that Connaught's vaccine contains the required FDA-approved DTP/HiB products, deliverable by a single injection, and is expected to provide protection against DTP and HiB diseases equivalent to that of previously licensed formulations of DTP/HiB vaccines. While the steps needed to administer the Connaught vaccine (which is to be combined before use), differ from those required to administer the Lederle vaccine (which is a pre-mixed vaccine packaged in the form of a single shot preparation), either approach results in a single injection of a combined DTP/HiB vaccine. Furthermore, the RFP specifically advised offerors that either a vaccine combination or a single shot preparation of DTP and HiB would meet the agency's needs; thus, the protester's assertion that Connaught's proposed vaccine combination was noncompliant with the solicitation is without merit.[4]

Lederle next asserts that CDC improperly relaxed the RFP's dosage requirements for Connaught, since Connaught was not required to provide the vaccine in 10-dose or 15-dose size vials. This argument also is without merit. The record shows that as approved by the FDA, the DTP offered by Connaught in a 10-dose size vial would be used to reconstitute and combine the single dose size vials of HiB vaccine (a freeze-dried preparation). Thus, as reconstituted, a single dose of the DTP/HiB vaccine offered by Connaught is equivalent to a single dose of the Lederle

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[4]Lederle also contends that the necessity for mixing the two separate products increases the likelihood of confusion, mistake, or waste in public health clinics thereby increasing the costs associated with reconstituting Connaught's products. Since the RFP allowed for a vaccine combination or a single shot, these allegations should have been raised prior to the time set for receipt of initial proposals. See 4 C.F.R. § 21.2(a)(1) (1993). In any event, the agency does not believe that these concerns have any basis in fact. According to the agency, this type of vaccine preparation is a routine office procedure and, given the cost savings, is worth any additional time needed to prepare the vaccine.

vaccine and the fact that Connaught's product is sold and priced in a 10-dose package rather than a single 10-dose size vial is immaterial. In any case, where no competitive prejudice is shown or is otherwise evident, our Office will not sustain a protest, even if a deficiency in the procurement is evident. See Latins American, Inc., 71 Comp. Gen. 436 (1992), 92-1 CPD ¶ 519; Anamet Labs., Inc., B-241002, Jan. 14, 1991, 91-1 CPD ¶ 31. While the RFP schedule sought fixed prices for 10-dose and 15-dose size vials, we find no evidence that Lederle was prejudiced by Connaught's use of a 10-dose package versus a 10-dose size vial. See Connaught Labs., Inc., B-235793, Oct. 11, 1989, 89-2 CPD ¶ 337.

The protester also contends that the CDC deviated from its longstanding practice of purchasing only those vaccines recommended by CDC's Advisory Committee on Immunization Practices (ACIP) by awarding the contract to Connaught, whose product lacks ACIP recommendation. As we understand ACIP's role in the vaccine procurement process, ACIP identifies those diseases against which children should be inoculated and makes recommendations as to vaccine types that may be used in the national immunization program. However, in doing so, ACIP does not recommend or mandate the purchase of particular brands of vaccines. In any event, as the protester itself acknowledges and our review of the solicitation confirms, the RFP did not require ACIP recommendation or approval as a precondition for consideration and award. To the extent Lederle complains that it was somehow misled by CDC action into believing that an ACIP recommendation was required even though the RFP did not contain any such requirement, Lederle has not shown how such action could have prejudiced the firm; again, prejudice is an essential element of every viable protest. Lithos Restoration, Ltd., 71 Comp. Gen. 367 (1992), 92-1 CPD ¶ 379.

The additional issues raised by the protester concern allegations that Connaught was given an unfair competitive advantage. In particular, Lederle alleges that CDC did not inform it that Connaught was competing for the award. Had Lederle known that Connaught had submitted a proposal, the protester asserts, it would have used a different pricing strategy in preparing its proposal. Lederle has cited no law or regulation, and we know of none, to support its position that CDC had a duty to disclose the number of proposals received in response to an RFP during negotiations. To the contrary, the FAR sets forth specific instructions on safeguarding information contained in proposals before a contract award is made. FAR §§ 15.411(b), 15.413-1; W.R. Moore, Brokerage, B-245729.4, July 27, 1992, 92-2 CPD ¶ 53.

Finally, our review shows that Lederle's claim that the agency improperly engaged in post-BAFO discussions with Connaught regarding evidence of an FDA license for its product, to its prejudice, have no basis in fact.

The protest is denied in part and dismissed in part.

Robert P. Murphy
Acting General Counsel