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Comptroller General
of the United States

United States General Accounting Office
Washington, DC 20548

Decision

Matter of: Schering Corporation

File: B-286329.3; B-286329.4

Date: February 2, 2001

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DIGEST

Protest of terms of solicitation for formulary drug item is denied where challenged requirements reasonably reflect agency's needs and evaluation scheme provides a reasonable basis for the evaluation of proposals for award.

DECISION

Schering Corporation protests the terms of request for proposals (RFP) No. RFP-797-NC-00-0073, issued by the Department of Veterans Affairs (VA) for non-sedating antihistamines (NSA). Schering contends that the solicitation is flawed for improperly grouping two of the protester's NSA formulations under the RFP. Schering also contends that the solicitation's weighted evaluation scheme does not provide a reasonable basis for the evaluation of proposals for award.

We deny the protest.

The RFP, issued on August 3, 2000, contemplates the award of a fixed-price contract, for a 1-year base period and four 1-year option periods, to the lowest-priced, responsible offeror under one of the solicitation's alternate contract line items (CLIN) for a single NSA (fexofenadine or loratadine) to meet stated VA, Indian Health Service (IHS),[1] and Department of Defense (DoD) oral solid dosage NSA requirements. This procurement is part of the agency's efforts to standardize the availability of pharmaceuticals and medical/surgical items, through the use of a

[1] The needs of a small number of IHS facilities, which are not at issue in this protest, will be served by this contract.

national formulary program.[2] The successful NSA will be added to the VA national drug formulary to be prescribed by VA physicians, and distributed by VA's medical facilities and Consolidated Mail Out Patient Pharmacies (CMOP), to current NSA users and new patients. If, however, a clinical need is cited by a VA physician for the patient's use of a different, non-formulary NSA, the prescribed non-formulary drug will be made available to the patient through the VA's non-formulary approval process. Agency Report at 2. For DoD, the national contract awarded under the RFP will only apply to initial (new patient) prescriptions for an NSA for direct care patients at a DoD military treatment facility (MTF).[3] The DoD formulary program, similar to the VA's, also provides for a non-formulary drug approval process based on clinical need. Id. The class of NSAs available under the formulary program is expected to "close" upon award of the national contract under the RFP; accordingly, during the contract period, medical facilities will be unable to add any other oral solid dosage NSA to their individual formularies. Supplemental Agency Report at 2.

The solicitation provides for competition between the two identified NSAs, fexofenadine and loratadine, which, the agency reports, have been determined by agency pharmacists to be therapeutically interchangeable. Agency Report at 8; Supplemental Agency Report at 6. Fexofenadine is manufactured by Aventis Pharmaceuticals and is marketed under the name Allegra®. Loratadine is manufactured by the protester, Schering, and is marketed under the name Claritin®. The RFP's pricing schedule, as amended, sets out separate CLINs for alternate offers of solid dosage formulations of the two NSAs. RFP amend. 7, attach. 1. For

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[2] A formulary is a list of prescription drugs, grouped by therapeutic class, which a health care organization prefers that its physicians prescribe. Standardizing medical and pharmaceutical items in a national formulary program anticipates concentrated buying power and volume-discount pricing. Agency Report at 1. Drugs are chosen for a formulary on the basis of their medical value and price. Defense Health Care: Fully Integrated Pharmacy System Would Improve Service and Cost-Effectiveness, (GAO/HEHS-98-176, June 12, 1998) at 2 n.1. The formulary system seeks to standardize drug use, ensure availability and consistency of the product for nationwide usage, increase the continuity of care, standardize the processes for evaluating the safety and efficacy of drugs, and manage cost growth. RFP § 1.2; VA Health Care: VA's Management of Drugs on its National Formulary, (GAO/HEHS-00-34, Dec. 14, 1999) at 4.

[3] DoD patients currently using another NSA drug will not have to convert to the awarded NSA. Additionally, NSA distribution by DoD's National Mail Order Program (NMOP), separate from MTF direct care, will not be limited to the awarded NSA. RFP amend. 2, § 3.2. The NMOP instead will continue to stock and distribute both formulary and non-formulary pharmaceutical items; the NMOP will benefit, however, from use of the anticipated lower national contract price of the successful NSA under the RFP. Id.

example, fexofenadine is solicited in two available forms: 180-mg tablets (for once-daily dosage) and 60-mg capsules or tablets (for twice-daily dosage). Separate CLINs (0001-0003, respectively) are provided in the RFP's schedule, as amended, to allow for alternate offers based on either the 180-mg or 60-mg formulations of fexofenadine, or both. Under CLIN 0003, which provides for an alternate offer of both fexofenadine formulations, prices for each of the two formulations (set out as CLINs 0003a and 0003b) are to be weighted to reflect the agencies' anticipated use of each formulation.[4]

The RFP pricing schedule also provides for alternate offers of Schering's loratadine product based on that NSA's two available oral solid dosage formulations: 10-mg loratadine tablets (for once-daily dosage), and 10-mg loratadine rapidly-disintegrating tablets (RDT) (also for once-daily dosage).[5] CLIN 0004 provides for offers of 10-mg loratadine tablets. A separate CLIN is not provided for the 10-mg loratadine RDT; the agency explains that this is due to the minimal anticipated use of the RDTs. Supplemental Agency Report at 4, 8. Rather, CLIN 0005 provides for an optional alternate offer of both the 10-mg loratadine tablets and the 10-mg loratadine RDTs.[6] For CLIN 0005, the offeror's proposed price for CLIN 0005a (for 10-mg loratadine tablets) is to be weighted at 99.5 percent; CLIN 0005b (for 10-mg

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[4] For evaluation purposes, the proposed price (under CLIN 0003a) for the 180-mg tablets is to be weighted at 70 percent, and the price (under CLIN 0003b) for the 60-mg capsules or tablets is to be weighted at 30 percent for a total CLIN 0003 evaluated price. RFP amend. 7, attach. 2, § 1(b).

[5] The 10-mg loratadine RDT, manufactured by Schering and marketed under the brand name Claritin RediTabs®, does not have to be swallowed like the 10-mg loratadine tablet, since the 10-mg loratadine RDT will dissolve on the patient's tongue. Aventis, the manufacturer of fexofenadine (Allegra®), does not currently manufacture an RDT of its NSA.

[6] Due to the role of DoD's Basic Core Formulary (BCF), DoD's intended treatment of an award under CLIN 0005, if one is made to Schering, is different from its intended action resulting from award under any other CLIN. The BCF mandates that all MTFs stock the drugs listed on the BCF; each MTF also maintains its own formulary in excess of BCF items. The agency reports that, due to only a minimal need for the RDTs, which would not justify mandating a continuous stock of the RDTs at all MTFs, DoD will not add the RDTs to its BCF, even if Schering wins the contract under CLIN 0005. RFP amend. 7 ¶ 3; Supplemental Contracting Officer's Statement at 2. Rather, in the event of a CLIN 0005 award, DoD would list on the BCF the 10-mg loratadine tablets, for which DoD has a substantial need, and would include on the BCF, in the notations section, an advisory to all MTFs that the RDTs were the basis of award of a national contract and that each MTF could decide to stock the approved item on its own formulary.

loratadine RDTs) is to be weighted at .5 percent.[7] RFP amend. 7, attach. 2, §§ (c), (d). Award is to be made to the responsible offeror that submits the lowest-priced offer, based on the average daily dose price of each CLIN.[8] Id. § 1.

The protester's challenge focuses on CLIN 0005. Schering contends that the agency's inclusion of the RDTs in the RFP in CLIN 0005 is improper because the tablets and RDTs are, in Schering's opinion, distinct products and therefore should not be included in the same procurement.[9] Schering cites as the primary difference the fact that the 10-mg loratadine RDT can dissolve on the patient's tongue prior to swallowing the medication, while the 10-mg loratadine tablet is swallowed whole. In support of its position, Schering points to the fact that the VA previously decided not to include the RDT formulation in this procurement on the ground that it did not meet the agency's needs. Schering also contends that if it does not win the contract on the basis of its CLIN 0005 offer (for the combination of tablets and RDTs), the effect of including the RDTs is to unfairly prevent Schering from marketing its RDTs during the contract period to the agencies to be served under the contract.

In response, the agency reports that it previously had decided to exclude the RDTs from the RFP (due to concerns that the RDT blister packaging would be inappropriate for elderly or dexterity-impaired patients, or for use in the mail out pharmacy operations, which often repackage medications for distribution). Agency Report at 4. Upon additional reflection, however, the agency concluded that including the 10-mg loratadine RDTs with the 10-mg loratadine tablets in this procurement would be proper because the two formulations are the "same exact drug." Agency Report at 8. The VA emphasizes that the tablets and RDTs have the

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[7] The agency reports that neither VA's nor DoD's historical prescription data for Schering's NSA RDT exceeds .5 percent of the total solid dosage NSAs (loratadine and fexofenadine) prescribed in 1999. Contracting Officer's Statement at 4.

[8] The average daily dose price is to be calculated by multiplying the unit price by the average daily dose (i.e., 1 or 2) indicated in the proposal's price schedule. RFP amend. 7, attach. 1, at 1. "To determine the lowest priced offer, the Government will compare the average daily dose prices for each individual line item." Id., attach. 2, § (d). The RFP further advises that if "any of the successful offeror's alternate offers have an evaluated average daily dose price that is lower than any other offeror's offer, the Government reserves the right to accept the alternate offer." Id. § 1(e).

[9] Schering argues that CLIN 0005 represents an improper bundling of requirements. Schering's argument, however, is misplaced. Rather, as the agency points out, improper bundling is associated with an inability of a protester to compete for the full, bundled requirement. See Pemco Aeroplex, Inc., B-280397, Sept. 25, 1998, 98-2 CPD ¶ 79 at 16. That is not the case here, though, since Schering clearly has the ability to compete on the basis of the challenged combined CLIN for its own products.

same content, dosage, safety, and efficacy, and are used interchangeably to treat the same symptoms. Id. The agency reports that, although the cited packaging limitations of the RDTs prevent their use as the sole loratadine formulation to be awarded the formulary contract, it grouped the RDTs with the other solid form of the same drug to allow for consideration of the RDTs in those cases where they do meet the agency's needs. In doing so, the agency feels it is reasonably increasing its flexibility in choosing the ultimately awarded CLIN, and in being able to freely prescribe either loratadine formulation, if award is made under that CLIN. Agency Report at 10. The agency also reasoned that the inclusion of CLIN 0005 reasonably increases the flexibility of the offeror in preparing alternate offers, if it chooses to have the RDTs considered for the contract award. Id. The agency contends that the stated RDT terms are not restrictive because Schering is not prevented from competing in any way.[10] Moreover, the agency contends, inclusion of the RDTs is necessary to ensure the integrity of the resulting award for a single solid dosage NSA drug on the agencies' formularies. The agency states, as was argued by both Aventis and Schering earlier in this procurement, that allowing NSA needs to be met outside this contract, or allowing another NSA formulation or comparable drug to remain fully available to physicians and patients after award, would thwart the formulary process and objectives, since that drug could compete for business anticipated under the contract, which would undercut the value of the award. Agency Report at 11; Supplemental Agency Report at 8.

A procuring agency is required to specify its needs and solicit offers in a manner designed to achieve full and open competition, and may include restrictive provisions or conditions in a solicitation only to the extent necessary to satisfy the agency's needs. 41 U.S.C. §§ 253a(a)(1)(A), (a)(2)(B) (1994). The determination of the government's needs and the best methods for accommodating those needs are generally the responsibility of the contracting agency; we will review such determinations to confirm that they are reasonably based. HG Properties A, L.P., B-284170 et seq. Mar. 3, 2000, 2000 CPD ¶ 36 at 10.

The protester does not refute the agency's medical judgment that its two NSA formulations (the 10-mg loratadine RDTs and tablets) are the same drug in terms of their content, dosage, safety and efficacy.[11] Instead, the protester asserts that the

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[10] In fact, the agency believes that Schering could face a potential substantial increase in RDT business if it wins on the basis of the combined (tablet and RDT) CLIN, since the firm could bring to the agencies' medical communities additional attention to its RDT formulation's receipt of a national contract. Supplemental Contracting Officer's Statement at 3; Supplemental Report at 13.

[11] In any event, we note that such a determination of therapeutic interchangeability involves a matter of the agency's medical judgments and policies and is not for our review. See Pfizer, Inc., B-276362, June 6, 1997, 97-1 CPD ¶ 205 at 7.

agency's decision to group them as it has done in CLIN 0005 in this solicitation was improper. We disagree.

The agency has determined, after consideration of arguments made by both Aventis and Schering in this regard, that in having solicited a high-volume formulary requirement in return for offers reflecting volume-discounted prices, it is obliged to take reasonable action to protect the integrity of the resulting formulary contract award.[12] To better ensure the anticipated volume of business for the successful NSA, the agency explains that it has included the protester's RDTs in the RFP to prevent any unfair opportunity for that loratadine formulation to compete for business with the awarded NSA during the contract term. Given that the two loratadine products are therapeutically interchangeable, and the potential that the protester's RDTs could compete with the drug selected under this contract if the RDTs were not included in the scope of this procurement, we believe the agency was reasonable to include them.[13]

The protester argues that the combined CLIN 0005 terms of the competition are unfairly restrictive as to Schering. Schering has failed to persuade us that the solicitation is unreasonably restrictive in any way. As the agency points out, the protester is in no way precluded from competing here. If Schering wins the formulary contract under CLIN 0005, it can market its RDTs to all of the agencies' facilities as a nationally awarded NSA that the facility should consider stocking, prescribing, and distributing to patients. Additionally, the potential for substantial business opportunities for its RDT formulation may remain for Schering, even if Schering does not win the formulary contract under CLIN 0005. For instance, as the agency reports, if Schering does not receive the formulary award, it can still market

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[12] Schering's contention that the agency must follow its initial determination to exclude the RDTs, because their packaging limitations kept them from being able to meet the agencies' full needs as a formulary drug item, is insufficient to sustain its protest. An agency may reconsider and revise its needs determination provided that its revised determination is reasonable, as we conclude the agency's is here.

[13] In fact, Schering itself argued early in this procurement for the agency to take action to protect the integrity of the award. Specifically, the protester had argued that the contract would be rendered "illusory" if another antihistamine's historical use data was not included in the RFP, because, without it, a potential antihistamine competitor could remain outside the formulary contract restrictions to compete for future VA and DoD needs. Schering contended that some of the needs for that antihistamine could be met under the NSA formulary contract. This left a question, Schering alleged, as to whether the government was in fact going to fulfill all of its NSA requirements with this contract. Schering Protest, B-286329, Sept. 22, 2000, at 8. (The agency subsequently made that data available to Schering and Schering withdrew its protest.)

each medical facility to inform doctors and potential patients that its RDTs are available for the clinical need of patients who have difficulty swallowing an NSA tablet.[14] Agency Report at 11. Similarly, win or lose, Schering's NSA RDTs can still be prescribed and distributed at MTFs to current users of the RDTs, and may be used to meet the pharmaceutical requirements of the NMOP, which will continue to stock alternate NSA products for distribution to patients prescribed that medication.[15] Accordingly, we find no basis to conclude that the challenged solicitation unduly restricts competition or Schering's ability to market or sell its product.

Schering is essentially contesting the business risk associated with losing the formulary contract. Some business risk, however, is inherent in every procurement, especially, as here, in a competitive procurement for a formulary contract for anticipated high-volume use of only one of two (fexofenadine or loratadine) competing NSAs. Nonetheless, it is the offeror's responsibility, in an exercise of its own professional expertise and business judgment, to take these business risks into account in deciding how to prepare its proposal and in determining what prices to propose. See C3, Inc., B-241983.2, Mar. 13, 1991, 91-1 CPD ¶ 279 at 4.

Schering next protests the weighted evaluation scheme set out in the solicitation for award. Schering argues that the .5-percent weighting provided by CLIN 0005 for evaluation of its RDT price indicates such insignificant product usage that it should not be considered in the evaluation.

For evaluation of price, stated evaluation factors must provide some reasonable basis for comparing the relative costs of competing proposals, so as to establish

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[14] We also note that under DoD's current BCF, Schering similarly would have to market to each MTF to include its product on its individual formulary because the BCF, prior to this award, has allowed the MTFs to pick one of several antihistamine products to stock.

[15] Further, as to Schering's challenge to the DoD's intention not to add the RDTs to its BCF even if Schering wins the award under CLIN 0005, we agree with the agency that, in light of the relatively small percentage of RDTs anticipated under the contract, it would be unreasonable to require DoD to list the 10-mg loratadine RDT separate from the protester's 10-mg loratadine tablet on the DoD's BCF. Schering also provides no reason to suggest that it would be appropriate to list the RDTs on the BCF and thereby mandate that each MTF be required to stock them. Given the circumstances, where the MTF is in the best position to know its patients' pharmaceutical needs, we find it reasonable that the MTFs determine whether to stock the RDTs to meet their needs for that formulation of loratadine. In any event, Schering can still market its product to the agencies, at least to demonstrate its ability to meet particular clinical needs of patients, or, regardless of need, for DoD's NMOP.

whether one offeror's proposal would be more or less costly than another's. See Health Servs. Int'l, Inc.; Apex Envtl., Inc., supra; Penn, Ferrara, Adler & Eichel, B-224224, Feb. 9, 1987, 87-1 CPD ¶ 134 at 3-4. Our review of the record confirms the reasonableness of the RFP's weighted factors for evaluation of the optional combined CLIN (0005) for 10-mg loratadine tablets and RDTs. The record shows that the weights assigned to the two formulations reflect a reasoned determination by the agency of its anticipated need for the evaluated sub-line items based upon relevant historical RDT prescription data. Although the .5-percent weighting is a minimal amount, it is not improper to consider it, as the protester argues, because it represents a legitimate estimate of the agencies' need (and the estimated resulting cost of the item to satisfy that need). In this regard, our review of the record shows that DoD's NSA requirements represent the vast majority of prescriptions to be issued under this contract and that RDT use by DoD was .5 percent (the same figure used for evaluation under CLIN 0005) of DoD's total NSA use in 1999, which amount is also expected, as a minimum, under the RFP. As such, we believe it serves as a reasonable basis for evaluation of the RDT sub-line item.[16] See Temps & Co., B-221846, June 9, 1986, 86-1 CPD ¶ 535 at 3-4 (use of weightings based on expected quantities of differently-priced items is a proper basis for price evaluation). Under the circumstances here, we find that the protester has provided no basis to question the reasonableness of the challenged solicitation terms.

The protest is denied.

Anthony H. Gamboa
Acting General Counsel

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[16] Based upon a mathematical error in amendment No. 5, Schering had argued that the RDT historical data shows only a .0007-percent (for the VA) and a .005-percent use of RDTs (by DoD) to satisfy the agencies' 1999 needs. The number of doses cited in that amendment, however, shows that the correct percentages, which have been confirmed by the agency, are .007 percent and .5 percent, respectively. Since, as stated above, we find the .5-percent weighting under CLIN 0005 for the RDT sub-line reasonably based on the anticipated minimum use of the RDTs for the vast majority (i.e., DoD's requirements) of NSA prescriptions anticipated under the RFP, we see no reason to question use of this estimate, even though it is slightly higher than the average of the VA and DoD prior RDT use.