GAO

Comptroller General
of the United States

United States General Accounting Office
Washington, DC 20548

Decision

Matter of: Novartis Pharmaceuticals Corporation

File: B-285038

Date: July 6, 2000

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DIGEST

Solicitation provision requesting the submission of an implementation plan as part of the technical proposal is not ambiguous.

DECISION

Novartis Pharmaceuticals Corporation protests the terms of request for proposals (RFP) No. 797-NC-00-0043, issued by the Department of Veterans Affairs (VA), for the drug clozapine. Novartis argues that the RFP is ambiguous with regard to the requirement that proposals address how the contractor will operate and maintain a clozapine registry.

We deny the protest.

The RFP provides for the award of a fixed-price contract with a base period of 1 year with four 1-year options. The RFP contemplates establishing a supply source that will provide an estimated 33,401 bottles of clozapine per year for purchase through VA's Pharmaceutical Prime Vendor (PPV) program.[1] RFP at 3.

[1] Under the PPV Program the VA awards separate contracts for the product distribution and for the source and purchase price for the product itself. Once a supply source is obtained for a product, it is distributed for use nationwide. RFP at 3.

Clozapine, originally manufactured by Novartis under their trademark Clozaril®, is used for the treatment of schizophrenia.[2] There are some serious potential risks of side effects from the use of clozapine. The most significant side effect is agranulocytosis or neutrapenia, a potentially fatal blood disorder that can be reversed if detected early. The agency explains that due to the risk of agranulocytosis, the Food and Drug Administration (FDA) "has restricted the distribution of clozapine since its introduction to the market" and mandated that a monitoring system be in place before clozapine can be distributed. Agency Report at 2.

Novartis, as the original manufacturer of clozapine, developed the first Clozapine National Registry, and agreed with FDA, upon the introduction in 1997 of a generic version of clozapine, to maintain a single database which includes a list of those individuals who should not be treated with clozapine again due to the occurrence of certain side effects. Id. at 2-3. The registry is normally checked prior to the beginning of treatment with clozapine, and all clozapine manufacturers, including Novartis, have access to the registry. Id. at 3. Accordingly, in addition to supplying clozapine, the contractor under the RFP will also be required to operate and maintain a clozapine registry. RFP at 3.

The RFP includes detailed instructions for the preparation of proposals. The solicitation requests that that offerors submit separate business and technical proposals. RFP at 31. The solicitation specifies that technical proposals shall include, among other things, an implementation plan. Id. The RFP (at 4) states that the implementation plan

> shall detail how and when the Clozapine registry database will be populated and submitted to the National Clozapine Coordinating Center in Dallas, Texas. This plan must also demonstrate how the offeror will accomplish all the requirements of the Clozapine registry (See Attachment G for suggested format for this plan).

The solicitation includes six pages detailing the minimum requirements for the operation and maintenance of a clozapine registry. RFP at 5-10.

The solicitation adds that the offerors should address each issue concerning their proposed implementation plans completely and in enough detail "to assure the Government of the offeror's understanding and capability to perform the cited requirements." RFP at 31. The RFP also states here that "[t]he Government will assess the realism and viability of the offeror's plan(s)," and that the implementation plan "will be evaluated to assure that the offeror demonstrates how all required tasks would be met." RFP at 31-32.

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[2] Novartis currently supplies virtually all of the clozapine required by the VA for its patients. Agency Report at 2 n.1.

The solicitation states that award will be made to the offeror submitting the proposal determined to be most advantageous to the agency. The RFP further provides that price will be the most important factor; followed by the past performance and implementation plan evaluation factors, which are equal in importance; and the small disadvantaged factor, which is significantly less important. RFP at 32.

Novartis protests that the solicitation is ambiguous concerning the RFP's requirement for the submission of an implementation plan. In this regard, the protester points out that each section of the RFP outlining the requirements for the implementation plan is followed by the parenthetical "[s]ee Attachment G for suggested format for this plan." RFP at 4, 31. Novartis argues that because attachment G is a one-page "milestone" chart, the RFP is unclear as to whether offerors are permitted to respond to the solicitation's requirements for an implementation plan in detail as the above-quoted sections of the RFP suggest, or are limited to completing the one-page chart set forth in attachment G.[3] Protester's Comments at 9-10.

When a dispute exists as to the actual meaning of a solicitation requirement, our Office will resolve the matter by reading the solicitation as a whole and in a manner that gives effect to all the provisions of the solicitation. Energy Maintenance Corp., B-223328, Aug. 27, 1986, 86-2 CPD ¶ 234 at 4.

As mentioned previously, the RFP contains six pages detailing the minimum requirements for the operation and maintenance of the clozapine registry, RFP at 5-10, and states that proposals are to include an implementation plan "demonstrat[ing] how the offeror will accomplish all the requirements of the Clozapine registry." RFP at 4. With regard to the evaluation of proposals, the RFP provides that the "realism and viability of the offeror's plan(s) will be considered, and that each offeror's implementation plan "will be evaluated to assure that [the] offeror demonstrates how all required tasks would be met." RFP at 31-32.

The protester's contention that the RFP may be read as limiting an offeror's implementation plan to a completed one-page attachment G is unreasonable. First, the protester's interpretation is simply inconsistent with the plain language of the parentheticals, where the attachment G format is "suggested" rather than mandated. Additionally, the parentheticals only suggest the attachment G format; there is no reference nor any indication that an offeror deciding to follow the attachment G format would be required to adhere to the attachment's one-page length. Most importantly, the protester's argument that the RFP could be interpreted as requiring

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[3] Attachment G consists of a 1-page chart entitled "implementation plan," with 4 columns entitled, among other things, "task" and "notes," and 10 rows, with the first row entitled "weeks 1 thru 4," and the following 9 rows entitled "week 5" through "week 13." RFP attach. G.

that offerors submit only a completed one-page attachment G renders meaningless the sections of the RFP described above which provide for the submission and evaluation of a reasonably detailed implementation plan.

In any event, the record reflects that Novartis was not misled in preparing its technical proposal by the RFP's reference to attachment G. That is, as pointed out by the agency, Novartis did exactly what the RFP and agency anticipated by following the format in attachment G in a submission of several pages describing its proposed approach to the RFP's requirements regarding the operation and maintenance of a clozapine registry. Given that Novartis was not misled by the ambiguity it asserts exists in the RFP, but rather prepared its technical proposal in the format anticipated by the agency, we fail to see how Novartis was prejudiced by the alleged ambiguity. See A-1 Postage Meters and Shipping Sys., B-266219, Feb. 7, 1996, 96-1 CPD ¶ 47 at 4.

Novartis argues for the first time in its supplemental comments filed with our Office that its implementation plan submission was actually a "half-a-loaf compromise," such that it has been prejudiced by the allegedly ambiguous RFP instructions regarding the implementation plan. Protester's Supplemental Comments, June 23, 2000, at 5. In our view, this argument cannot be reconciled with Novartis's previous assertions that the RFP was ambiguous in that it could reasonably be read in a manner not anticipated by the agency, that is, as limiting offerors to the submission of only a completed one-page attachment G. It is clear from the record that Novartis did not read the solicitation in this alternative manner, and we find Novartis's self-serving contention that it was somehow misled by the RFP, even though its proposal included an implementation plan in the format anticipated by the agency and consistent with the agency's reading (and one of Novartis's readings) of the RFP, to be insufficient to support a finding of prejudice.[4] See Browning-Ferris Indus. of the S. Atl., Inc.; Reliable Trash Serv. Co. of Md., Inc., B-217073, B-218131, Apr. 9, 1985, 85-1 CPD ¶ 406 at 4.

The protest is denied.

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[4] Novartis also complains that the agency failed to develop acquisition and evaluation plans for this procurement. Protester's Comments at 11-12; Protester's Supplemental Comments at 6. However, since the protester does not claim that it was prejudiced in any way by this alleged failure, we will not consider Novartis's complaints in this regard further. See Champion Bus. Servs., Inc., B-283927, Jan. 24, 2000, 2000 CPD ¶ ___ at 3 n.2.