01199

DECISION

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

FILE: B-186731 DATE: October 6, 1976

MATTER OF: Marion Health and Safety, Inc.

DIGEST:

1. Where Defense Medical Materiel Board determined that other commercial product was acceptable alternative to previously procured item, DSA's revision of military specification to reflect that two commercially available items meet actual minimum needs of Government was proper, notwithstanding that protester believes its product has superior qualities.

2. Where alternative acceptable products reflect divergent solutions to basic requirement, specifications stating Government's alternative minimum requirements are not improper, simply because some provisions contained therein apply only to one or other of two possible approaches.

Marion Health and Safety, Inc. (Marion) protests the use of specification MIL-T-0036815C by the Defense Personnel Support Center (DSA) for the procurement of "biological culture sample tubes," or sample tubes. This protest was timely filed in connection with DSA's procurement of sample tubes under its solicitation DSA120-76-R-2070.

Marion presents multiple grounds for protesting the specification, which is a revision of a previous specification, MIL-T-36815B, which apparently described only Marion's commercial product. The specification was revised for the specific purpose of allowing for acceptance of a commercial item manufactured by the Precision Dynamics Corporation (Precision). The change was made to open the procurement to competition, after the Defense Medical Materiel Board had determined that the Precision product was an acceptable alternative.

Simply explained, a biological culture sample tube consists of a plastic cap connected to a cotton swab. The swab is normally contained in a plastic tube approximately 6 inches in length, with a reservoir at the closed end. The reservoir contains culture media. The package is designed so that in ordinary use

the sterilized swab is removed from the tubular container, applied to collect a biological sample, and reinserted into the tube. The reservoir is opened and penetrated, or broken, freeing the media to sustain biological activity while the sample is transported to a laboratory for analysis.

Marion markets its product under the tradename, "Culturette." Precision uses the name, "Securline."

Marion complains that the provisions of paragraph 3.1 of the specifications discriminate against its product, and favor that offered by Precision. The paragraph cited provides:

> "3.1 Material. Material shall be as hereinafter specified. If material is not specified, it shall be suitable for its intended function.
>
> "3.1.1 Tip. Cotton for applicator tip shall conform to JJJ-C-561, except sterility requirement shall not apply.
>
> "3.1.2 Plug separator. Non-woven fabric for plug separator shall be polyester or cotton in accordance with material characteristics of DDD-B-70, paragraph 3.1
>
> "3.1.3 Ampul. Glass for ampul shall be in accordance with type NP of the USP."

We cannot agree with Marion's view that these provisions are discriminatory -- that "under the specification a competitor's product need only be suitable for its intended function." It is true that subparagraphs 3.1.2 and 3.1.3 apply only to the Marion Culturette, but that is so because the Culturette contains two additional parts: the plug separator and the ampul. Paragraph 3.1 defines the kinds of materials which may be used. The material for the cap, applicator, and outer tube is not specified, and must only be suitable for their intended use. Both designs incorporate an applicator tip, and must conform to the requirement of subparagraph 3.1.1. The Culturette reservoir is comprised of an ampul, or sealed glass tube fitted inside the outer plastic tube, which serves the function of containing the media until used. The same result is obtained in the Securline culture tube by "crimping" the plastic tube to

form a sealed compartment. The additional parts are not required. Plainly, the cited specification defines only types of materials which must be used. We do not construe it as requiring that an ampul and plug separator be employed. Nor can it be said that the Defense Medical Materiel Board and DSA have acted arbitrarily in requiring that manufacturers using a Marion type reservoir meet the materials specifications for the ampul and plug separator.

Marion complains that subparagraph 3.2.1 requires only that one end of the plastic outer tube be sealed, so that regarding sample tubes of the Precision design (where both ends of the reservoir have crimped seals) there is no requirement that the interior or "upper" seal not leak. This is not true since subparagraph 3.2.1.3 requires that the tube "shall be sealed above the transport media to form a media chamber and to keep applicator tip from the media until the seal is pressed or squeezed."

Marion argues that the last sentence of subparagraph 3.2.1 requires that the plastic outer tube "shall be free of deformation which will impede removal and replacement of the swab." Marion views this as requiring a completely cylindrical tube. However, we agree with DSA that the specification requires only the absence of impeding deformation.

The protester contends that subparagraph 3.2.1.1 is ambiguous by requiring only the use of a "suitable" volatile solvent or a "suitable" adhesive to bond the cotton applicator tip to the applicator. Evidently, this requirement replaced the earlier specification for the use of "Fuller's adhesive X 3801 or better." As DSA states, "suitable" requires that the bonding agent be appropriate to its intended use, and in the context of its application here, to adequately secure the swab tip to the swab without exhibiting toxic characteristics. If as Marion maintains, use of Fuller's adhesive X 3801 or better is necessary to avoid toxic characteristics, then "or better" has the same latitude as "suitable." We can perceive no advantage in identifying a specific adhesive where the agency itself has determined that such specificity is not required to meet its minimum needs.

Marion complains that it is required to comply with the provisions of subparagraph 3.2.1.2, entitled "separator plug", requiring that its plug "absorb the media which is released when the ampul is crushed" and "provide enriched moisture to the swab tip", but that no similar requirement is imposed on sample tubes using Amies media, such as Precision's Securline tube. While no such requirement is imposed, DSA explains this difference as follows:

> "The specification requirement that the separator plug provide enriched moisture to the swab tip is based on the fact that the swab tip in the Marion product /or any product using a similar design to compensate for the use of a low viscosity media/ is not directly immersed in the media, but rather obtains the moisture to sustain microbial viability essentially through contact with the separator plug. The Precision item, on the other hand, is so designed that the swab tip itself is immersed in the media. * * */Marion's/ allegation fails to take into account that provision of paragraph 3.2.1.3 which requires that the size of the media chamber be such that the specified amount of media is sufficient to cover the applicator tip when instructions are followed, and the further requirement of paragraph 3.6 that the tube be capable of sustaining microbial viability for a specified period. The Precision item, or any other competitor's item, would have to comply with these requirements."

We note, in this regard, that the instructions on the Securline package direct the user to break the compartment seal and "insert swab into medium." The Marion design utilizes modified Stuart's transport media, which has an observably lower viscosity than does the Amies media. Insertion of the swab as directed by the Securline instructions does result in its being covered. The swab may not absorb the media as readily as would the Marion swab, but it does absorb it. Also, the swab may not remain completely covered if the tube is not stored in an upright position.

Even though substantial differences may exist between the alternative types of sample tubes available, the function of the specifications is to state the Government's minimum needs, and we will not substitute our judgment for that of the Defense Medical Materiel Board on this matter. As DSA has indicated, any tube offered must be capable of sustained microbial activity for not less than 72 hours, when used as directed.

In this connection Marion also suggests that the directions on the Securline package are ambiguous. We have examined the instructions, and in particular, the illustration included therein, and contrary to Marion's claim, the instructions can be followed if the tube is held as shown.

Marion asserts that "The requirement /that the media be able to sustain microbial viability/ has been deleted from the * * * /present/ specification and since there is no formulation requirement for either Stuarts Modified or Amies media, there appears to be no way to assure the microbial viability of the culture." This requirement is in fact contained in paragraph 3.6 of the present specification, which requires that microbial activity be sustained in tests of 72 hours duration, under prescribed testing standards.

It is asserted by Marion that although paragraph 3.3 states that "nominal dimensions shall be as shown in Table I", the dimensions shown in Table I are given without tolerances. We agree with DSA that nominal implies that the non-critical dimensions given are approximate figures, and that reasonable variation is permitted. Indeed, inclusion of tolerances would indicate that the figures are not merely nominal, and may not exceed the maximum and minimum dimensions specified.

The protester objects to reduction of the required shelf life of the sample tubes to 18 months, from the 24 month requirement imposed under the prior specification. As Marion admits, this requirement is within the discretion of DSA to determine, taking into account its assessment of what is required in the best interests of the Government. DSA states that this change was coordinated with the Defense Medical Materiel Board.

In response, Marion has suggested that DSA's coordination with the Defense Medical Materiel Board may have been less

than adequate, and requests that we investigate this matter. We note that Marion was well aware of any basis for protest it may have had on these grounds at the time this protest was initially filed, and made no objection at that time. See Bid Protest Procedures, 4 C.F.R. § 20.2(b)(2) (1976). The issue was first raised by Marion after proposals were submitted, in connection with its rebuttal to the agency report. In addition, we find no basis for questioning DSA's determination that the shorter shelf life is in the best interests of the Government.

Marion next complains that specification paragraph 4.3, Examination, adds an additional examination requirement to the prior specification, and it questions whether the additional sentence is necessary "inasmuch as we are already required to comply with the specification and a list of defects in Table IV." In this connection, DSA reports that the reference to "Table IV" was a typographical error and that the list of defects, in any event, was not intended to be all-inclusive.

Marion also questions the meaning of classified defect No. 108, which states: "applicator swab not separated from ampul and media (as applicable)." Again the protester views this as including a requirement applicable only to it. We disagree. As adequately explained by DSA, this requirement "is intended to apply to both the Marion item and the Precision item. Paragraph 3.2.1.2 * * * requires the swab tip to be separated from the media ampul by the separator plug * * * while paragraph 3.2.1.3 requires the swab tip to be separated from the media by the upper seal of the media chamber (Precision item)."

Marion argues that since:

> "* * * the classification of defects is designed to recognize areas of possible problems in the product furnished and since a product using Aries media depends on the rupture of the top seal for introduction of the swab to the media, we would suggest that in view of the fact that the bottom seal may rupture before the top seal during the squeezing operation * * * that such an occurrence /should/ be listed as a defect."

DSA accepts this as a good suggestion, and has indicated that it expects to incorporate such an express requirement in future

solicitations. However, DSA does not believe that other than prospective action is required, since in any event the suggested type of failure would be noted if it occurred and would be listed as a paragraph 3.10 "defect which * * * may impair * * * /the/ serviceability" of the sample tube. We agree.

The protester contends that the leakage test described in paragraph 4.4.3 can be realistically applied only to its product, which it views as discriminatory. The disputed provision reads as follows:

> "Test samples of tubes without components shall be filled with 3-4 ml. of water containing a suitable indicator. These tubes shall be allowed to stand upright on white absorbent paper for not less than 2 hours. Bottom of the tubes shall then be examined for wetness and the paper shall be noted for color spots indicating leakage."

DSA admits that the prescribed test cannot be literally applied to the Precision item, but argues that "the same degree of quality assurance would be exercised to assure the integrity of the Precision item's bottom seal." Moreover, DSA maintains the integrity of the bottom seal in the Culturette cannot be determined by external examination of the finished sample tube, since until broken, the media is contained in the ampul, and is not in contact with the plastic outer container. The Securline, on the otherhand, contains the media within the crimped tube, and its integrity is immediately apparent on examination of the tube.

We agree with Marion that the specification is written to apply to sample tubes utilizing either Amies or modified Stuart's media and that if the test is to be applied to only one type of sample tube, it should be revised. In view of the various requirements already mentioned, requiring that Precision produce a functional product, we believe that Marion has not been prejudiced by this omission because the deficiency would be corrected by limiting the test to Stuart's media sample tubes, and requiring external examination of the Amies media tubes for wetness.

Next Marion argues that in adopting the new specification, DSA has eliminated paragraph 3.5 of the prior specification, dealing with packaging, packing and marking. As DSA noted such requirements are now contained in Section 5 of the specification.

Finally, Marion objects that the new specification does not provide a formulation requirement for the transport media, noting that there are various formulations of Stuart's and Amies media, and each has modified formulas. DSA's position is that it has specified the functional requirements to be met, and the test procedure for determining whether the media will properly sustain the required biological culture, so that rigid formulation requirements are not considered essential. It is of course necessary that the media be classifiable as being of either the Stuart's or Amies class of media, as required in paragraph 3.2.1.3.

Manifestly, DSA has determined that the minimum needs of the Government can be met through less restrictive specifications than it has employed in the past, allowing competition by firms willing to manufacture sample tubes compatible with the Precision offered product. This is in principle consistent with the basic statutory requirement for competition and with sound procurement policy. Although we have considered Marion's views, we find no support for its assertion that it has been treated unfairly and there is no reason to conclude that DSA abused its discretion in establishing the new competitive specifications.

We are by letter to the Director of the Defense Supply Agency today calling attention to the need to revise paragraph 4.4.3 of the specification. Nevertheless, we find no sufficient reason to justify resoliciting the procurement.

Accordingly, Marion's protest is denied.

Deputy Comptroller General
of the United States