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

B-176091

JAN 16 1973

Mr. John Novic, President
Clinical Supply Corporation
117 South Second Avenue
Mount Vernon, New York 10550

Dear Mr. Novic:

Reference is made to your letter of August 4, 1972, and prior correspondence, protesting against rejection of your offers under three solicitations, DSA120-72-B-1828, -1987 and -2245, issued by the Defense Personnel Support Center (DPSC), Philadelphia, Pennsylvania, for braided surgical silk sutures. In each instance your offer was rejected as nonresponsive by virtue of noncompliance with a material requirement of the solicitation that the offeror submit with his bid evidence that he is in possession of a "New Drug Application" (NDA) approved by the Food and Drug Administration (FDA) for the manufacture of this type suture.

You contend that the solicitation requirement that offerors possess an approved NDA for the sutures to be procured was unreasonable because it added nothing to the quality of the product as evidenced by the fact that you are currently producing the identical sutures called for by the protested solicitations under existing DPSC contracts. You also maintain that in any case you satisfied FDA requirements to permit continued commercial marketing of your sutures because you are the holder of a "deemed approved" new drug application in accordance with applicable FDA regulations and that hence your offer should not have been declared nonresponsive. In this regard, you point out that you submitted an abbreviated NDA to FDA on March 14, 1972, which you maintain is all that is required by FDA to permit continued marketing of your sutures.

You further allege that the requirement for an approved NDA under the instant solicitations was inserted specifically to favor Ethicon, Inc., the only current holder of an approved NDA for the subject sutures, and that the requirement was inserted "only after" Ethicon obtained the required approval. In furtherance of this allegation you point to a recent open market purchase from Ethicon of the subject sutures at a price in excess of that for which the identical sutures could have been obtained under the option provisions of an existing Clinical contract. Also you point to two other recent DPSC solicitations for different types of sutures, contending in essence that those solicitations either did or did not require approved

NDA's according to whether or not Ethicon had previously secured approval with respect to those specific sutures and without regard for FDA NDA requirements.

Finally, you contend that DPSC technical personnel lack the competence and the equipment to test the acceptability of contract-supplied sutures and in any event that the NDA requirement cannot be viewed as an acceptable substitute for acceptance testing. You cite in this regard a recent decision of the Armed Services Board of Contract Appeals (ASBCA) in Clinical's favor which you contend holds that such technical competence is lacking in DPSC personnel. You also make general, undocumented allegations concerning what you consider to be conflicts of interest and generally unethical conduct on the part of specific DPSC personnel.

The Defense Supply Agency administrative report, including the statement of the DPSC contracting officer, summarizes the history leading up to the requirement by FDA that manufacturers of certain enumerated drugs and medical products (such as the sutures here involved) classified as "new drugs" secure approval of their products from the dual standpoints of safety and effectiveness by means of FDA approval of properly documented NDA's. With respect to "deemed approved" manufacturers, it is reported that manufacturers of medical products covered by the NDA requirement who had secured FDA approval prior to 1962, when the effectiveness criterion was added to the preexisting safety criterion, are considered to be "deemed approved" without the necessity of submission of a new NDA once effectiveness data on the pre-1962 approval product has been evaluated and found sufficient. It is also reported that FDA has not interfered with the commercial marketing of products classified as "new drugs" by FDA but which are not entitled to "deemed approved" status and for which no new NDA has been filed or approved, pending NDA submission.

With respect to the requirement in the complained of DPSC solicitations that an approved NDA be submitted with the bid, notwithstanding that prior contracts (some of which are still outstanding) contained no such requirement and that the requirement represents a more stringent application of FDA's rules than FDA itself imposes, the report points out that the Defense Medical Material Board (DMMB), charged with the responsibility within the Department of Defense (DOD) of setting procurement policy with respect to items related to medical care, determined in February 1971 that:

> "* * * thereafter an approved new drug application would be a requirement in a DPSC drug procurement once FDA announced

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> that that drug item was considered by it to be a 'new drug' and that its manufacture and marketing required an FDA approved new drug application."

It is stated that this determination was made following consultation with FDA wherein FDA advised DSSB members, among other things, that the fact that FDA did not interfere with commercial marketing of a "new drug" not properly approved "should not be construed as an endorsement for the medical profession to use the drug of that manufacturer" and that the determination whether DOD should authorize use of such drugs rested with DOD.

On the question of the application of this general policy to the procurements of silk braided sutures of which you complain, the report states that on November 11, 1971, FDA published in 36 Federal Register 21612 Drug Efficacy Study Implementation (DESI 4725) which designated five types of surgical sutures, including nonabsorbable braided silk, as "new drugs" and further listed the names and NDA numbers of the approved manufacturers of those sutures as having been evaluated as "effective" in accordance with FDA procedure. On the strength of this FDA determination, the DSSB advised DPSC in early December 1971 that all sutures covered by the November 11 Federal Register publication would be procured subject to the NDA requirement.

The report states further that Ethicon first secured NDA approval for braided silk sutures in March 1958 and flatly disputes your contention that Clinical is a "deemed approved" braided silk suture manufacturer on the strength of advice from FDA that Clinical has not filed any NDA's save its application in March 1972, cited by you, which as of the date of the report had not been approved.

With respect to your allegations concerning the competence and ethics of DPSC personnel, the report denies that the cited ASBCA decision made any comment with respect to the competence of DPSC personnel and dismisses your other comments as "insinuations." Concerning the recent purchase of silk sutures from Ethicon, notwithstanding a less expensive option right under an existing Clinical contract, the report points out that this procurement was made following the FDA "new drug" determination with respect to silk braided sutures and that, therefore, possession of an approved NDA on the part of the successful offeror was required in accordance with the DSSB determination. In justification of soliciting only Ethicon for this requirement, the report states that the procurement was made on an urgency basis, thereby implying that time did not permit the seeking of NDA approval by other firms.

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For reasons set out below, we conclude that the approved NDA requirement for the silk sutures here involved is not subject to question.

As indicated above, the DSSB is responsible for setting DOD procurement policy with respect to medical items. This responsibility is derived from DOD Directive 5194.1B, May 26, 1965, which states one of the essential functions of the Board to be to--

> "Prepare essential characteristics * * * for each item of medical material entering the Department of Defense Supply System;"

We have previously held that "A determination by the DSSB concerning any aspect of professional medical and items constitutes a technical or scientific decision as to the minimum needs of the Government" and that "DPSC has no option other than to adhere to the determinations of the DSSB." B-173683, November 29, 1971. The cited decision concluded that the DSSB imposed specification restrictions in that case represented "a valid and reasonable restriction on competition"--a conclusion which we also conclude the instant case warrants. See, also, 50 Comp. Gen. 209, 212 (1970) and B-150387, July 9, 1963. Inasmuch as the general rule of our Office is that specification and bidder qualification determinations are primarily the responsibility of the procuring agency subject to question by us only where unreasonable or arbitrary, we find no basis for questioning the administrative action in this case, even though it represents a requirement not included in past procurements. See 49 Comp. Gen. 857, 862 (1970); 45 id. 365 (1965). Also, in the absence of contrary evidence in the record before us, we must accept DPSC's statement on the question of Clinical's lack of "deemed approved" NDA status.

With respect to your contention that NDA approvals are used by DPSC to favor Ethicon, we think that the fact that the DSSB determination to apply an across-the-board approved NDA requirement was made some 9 months before FDA published notice that braided silk sutures were subject to the requirement is sufficient indication of the good faith of both the DSSB and the DPSC. Similarly, the administrative report indicates that approved NDA's are required by DPSC only for the five sutures listed in the November 11, 1971, Federal Register publication (i.e., surgilene nonabsorbable, polyester fiber sutures; chromic beef serosa collagen absorbable gut sutures; plain absorbable gut sutures; and braided nylon nonabsorbable sutures, in addition to braided silk

sutures) which is consistent with the DSCB determination that only items listed by FDA as "new drugs" need be subjected to the NDA requirement.

On the question of the competence of DPSC equipment and personnel and the bearing the recent ASBCA decision in Clinical's favor has on this question, our reading of the decision indicates that it was rendered in Clinical's favor on the basis of the Government's failure to sustain its burden of proving that the sutures supplied under the contract there in dispute did not meet contract requirements. As such, the decision expressed no binding opinion on the adequacy of DPSC personnel, equipment, or procedures but merely concluded that the evidence presented at the hearing favored Clinical. Therefore, the decision is not entitled to any consideration in determining DPSC competence in the area of acceptance testing. Your other allegations about DPSC personnel are unsubstantiated and therefore must be dismissed without further comment.

In accordance with the above considerations, your protest must be denied.

Very truly yours,

PAUL G. DEMBLING

For the Comptroller General
of the United States