EXHIBIT 19

DEPARTMENT OF DEFENSE POLICIES AND PROCEDURES FOR PREPARATION OF SPECIFICATIONS TO INSURE ACQUISITION OF QUALITY MEDICAL MATERIAL

The policy of the Department of Defense is to purchase quality drugs to meet designated delivery schedules from the lowest, responsive, responsible supplier (bidder) and in accordance with the procedures of the Armed Services Procurement Regulation. Drugs may be generic or brand name, but provision must be made for a sufficient span and latitude of high quality drugs to permit our military physicians to make a deliberate choice and not a forced decision. To carry out this function, the Department of Defense established the Defense Medical Materiel Board, composed of the Surgeons General of the three Military Medical Services and a staff of highly qualified professional personnel. The Board has the assigned responsibility to determine those chemical, physical and physiological characteristics considered as mandatory requirements of a drug or biological necessary to meet the professional needs of the physician and dentist to adequately treat diseased conditions of patients under their care. In conformance with directives issued by the Department of Defense, the Board designates pharmaceuticals by generic name, except in those instances where professional knowledge and experience has demonstrated that only the product of a specific manufacturer (brand name) can be relied upon to produce the desired consistent physiological effects.

As evidence of the above, the Defense Medical Materiel Board has used its authority to designate specific acceptable sources of supply sparingly. As of 30 December 1966, of the over 1200 items of drugs and biologicals, only 31 items have been designated by the Board for sole source procurement. These items include 10 pharmaceutical products, 8 recently adoptel oral contraceptive tablets and 13 laboratory reagents. There are 409 items which are not specifically designated by the Board as sole source, but which, although solicited competitively, are procured from a single source. Specifications are written for the generic item and the product is so solicited. Notices of impending procurements over $10,000 are published in the Department of Commerce, Commerce Business Daily and specifications and solicitations are forwarded to prospective suppliers in an attempt to broaden the base and achieve competition. However, either because of production capability, pharmaceutical know-how, the initial investment expense, patents or licensing, only one source has responded to a solicitation.

The drugs (as well as other medical items) which are to be procured by DPSC are selected or standardized by the DMMB. On standardizing a drug, the DMMB identifies the characteristics and attributes which the item must possess to satisfy the medical professional needs. Based on the guidance furnished by DMMB, DPSC must draft specifications which will permit the acquisition, by generic description, of that drug possessing the quality required for medical professional needs. Initially, the data for these specifications is obtained from the information supplied by the DMMB, from the contents of the compendia, from FDA, from any available literature, from the in-house knowledge derived from experience with the same or similar items and from those producers who have supplied the item in question to the Military Departments and whose item has been found to be acceptable by the DMMB.

The use of data from the supplier whose product has been determined to be acceptable is in many instances both necessary and desirable if a quality product is to be obtained. The Department of Defense does not have an original research program in drugs from which to draw some of the essential information. The data from the sources mentioned above selectively forms the basis for the specifications after it has been screened and evaluated to determine which is relevant to and reasonably necessary for assuring the acquisition of quality drugs. Specifications are continually reviewed and strengthened with a view toward improving the probabilities of obtaining, regardless of source, the quality product required. The program for the continuing reevaluation of specifications depends for its data not only upon the sources previously used, but also on the test reports and other information received through the DPSC con-