ENCLOSURE 2

INFORMATION ON THE DEVELOPMENT OF SPECIFICATIONS FOR PRESCRIPTION DRUGS BY DPSC[1]

The development of specifications by the Medical Directorate, DPSC, is a complex function because there are few standards in industry that can be used for procurement purposes. Further, there is no Government agency that develops technical data on drug products which can be used to develop specifications for competitive procurement. Accordingly, a significant portion of the technical data for prescription drugs used by DPSC, the FDA, the National Institutes of Health, and the USP and NF must initially be obtained from the drug manufacturers.

The data included in DPSC specifications contain information on purity, safety, effectiveness, and stability standards. In competitive procurement comprehensive standards must be clearly established to eliminate misunderstandings. DPSC often finds it necessary to designate more stringent product standards than those applicable to commerce because of the possibility of long term storage and transportation under adverse conditions and the need to assure that the product will retain its safety and effectiveness until time of use. These needs tend to be more stringent to meet the many vicissitudes of military usage rather than civilian usage.

DPSC has learned that quality products cannot regularly be procured by simply referencing the USP and NF. DPSC has had many experiences where drug products complying with USP or NF standards, have not been suitable in actual use.