

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10731

"WE CANNOT PROCURE COMPETITIVELY WITHOUT A GENERIC SPECIFICATION. OUR STANDARDS ARE BASICALLY THOSE OF THE U.S.P. AND N.F., SUPPLEMENTED WITH SUCH ADDITIONAL STANDARDS AS ARE NECESSARY TO ENSURE SUITABILITY NOT ONLY AT THE TIME OF PROCUREMENT, BUT ALSO FOLLOWING POSSIBLE LONG-TERM STORAGE THROUGHOUT THE WORLD IN ARCTIC, TEMPERATE, OR TORRID ZONES. MANY OF OUR SPECIFICATIONS INCLUDE STANDARDS WHICH HAVE BEEN OBTAINED FROM INDUSTRY DURING THE STANDARDIZATION PROCEDURE. IF WE ARE TO OBTAIN SUITABLE MATERIAL COMPETITIVELY, WE MUST INCLUDE THESE DETAILS IN ORDER TO PROVIDE OTHER THAN PRODUCT ORIGINATORS WITH THE NECESSARY PRODUCT INFORMATION."

AS BRIG. GEN. HAYES STATES, THE DPSC STANDARDS ARE BASICALLY THOSE OF THE OFFICIAL COMPENDIA SIMPLY SUPPLEMENTED WITH ADDITIONAL STANDARDS PECULIAR TO THE SPECIAL NEEDS OF THE MILITARY. CONSEQUENTLY, ALTHOUGH ADDITIONAL SPECIFICATIONS MAY BE ADOPTED BY THE DPSC, THIS DOES NOT MEAN THAT THE OFFICIAL COMPENDIA STANDARDS ARE INADEQUATE AS APPLIED TO DRUG PRODUCTS AS INTENDED FOR USE BY THE GENERAL PUBLIC. FOR EXAMPLE, THE CRITICAL CONSIDERATION OF MINIMIZING UNNECESSARY WEIGHT MIGHT NECESSITATE SPECIFYING THE USE OF A LIGHT-WEIGHT PLASTIC CONTAINER FOR DRUG PRODUCTS TO BE CARRIED ON BOARD SPACECRAFT. ON THE OTHER HAND, THE USE OF SOMEWHAT HEAVIER CONTAINERS, SUCH AS THOSE MADE OF GLASS, WOULD BE PERFECTLY APPROPRIATE FOR USE IN PACKAGING DRUG PRODUCTS INTENDED FOR NORMAL CHANNELS OF DISTRIBUTION.

HOWEVER, THE SPEECHES AND ARTICLES BY DPSC OFFICIALS PREVIOUSLY MENTIONED, HAVE SUGGESTED THAT DEFICIENCIES IN PRODUCTS AND MANUFACTURERS ARE NOT SIMPLY RELATED TO THE SPECIAL NEEDS OF THE MILITARY, BUT THAT THEY ARE FAR MORE SERIOUS AND REPRESENT A PUBLIC HEALTH HAZARD.