

specification requirements developed by DPSC and later adopted by the USP or NF.

The DPSC specification for Aluminum Hydroxide Gel, USP, has included a bacterial count requirement since 1953. This requirement was included in the USP on September 1, 1970.

By March 1963, DPSC specifications for Phenacetin and Phenacetin-containing drugs included limits for two contaminants which had been implicated in causing kidney damage. These requirements were included in the USP in May 1963 and September 1965.

The DPSC specification for Carbarsone Tablets have included a limit on arsanilic acid, which causes a toxic reaction, since June 1962. The NF included this limit effective April 1971.

The DPSC specifications are used by the Veterans Administration and the Public Health Service with modifications generally limited to packaging and packing requirements. DPSC also receives requests for its specifications from States, cities and municipalities, and insurance companies.

An important by-product of DPSC's definitive specification requirements is that they furnish potential competitors with highly detailed standards of purity and quality not available from other sources. DPSC specifications have aided small business firms in producing and becoming successful contractors for drug items such as acetaminophen elixir and tablets; hydrocortisone cream; belladonna alkaloids and phenobarbital tablets; and lanolated, water dispersible mineral oil.

1

Source: DPSC booklet prepared for the Inter-Agency Study for Medical and Nonperishable Subsistence Items.