

remainder, about 535 items, have been supplied by single sources. Of these, competitive procurement of 386 is limited by patents or by FDA regulatory requirements which preclude marketing without an approved new drug application or anti-biotic certification. The remaining 149 items have no apparent legal or regulatory restrictions that would preclude interested firms from submitting bids on DPSC requirements.

In 1969 and 1971 DPSC made a widespread effort to develop competition on a large number of drug items but the responses were few and disappointing.

Basically DPSC's specifications require full compliance with the product standards and requirements set forth in the United States Pharmacopeia (USP) or National Formulary (NF). But additional requirements are often included to provide assurance that items manufactured will have needed characteristics for such requirements as potency and purity, from the time of manufacture to use. Only about 50 percent of the drug items managed centrally by DPSC and 65 percent of those managed centrally by VA are monographed in the USP and NF.

The use of manufacturers' data by DPSC in the development of its specifications could result in including requirements which are not essential to producing a comparable product or which do not contribute to its medical usefulness. However, DPSC includes in its solicitation packages a Specification Analysis Sheet for potential suppliers to submit comments on the specification requirements and those that bidders claim are unnecessary or unduly restrictive are evaluated by DPSC.