classification was requested by the Air Force in 1963. The item is a commercially available antacid which was marketed under the trade name of "Titralac tablets" by Riker Laboratories, Inc., Northridge, Calif. It is used primarily in the treatment of peptic ulcers (gastric and duodenal) and gastric hyperacidity.

In 1963 the Air Force used a statistical sampling technique to evaluate usage of nonstandard drugs. Upon noting that over $2,500 was being spent on this antacid that year by a selected group of 21 hospitals, the Air Force marked the drug for review. Air Force professional and logistic personnel concurred that there would be a continued requirement for a drug of this type, and that demand and use rates could be expected to increase, or at least remain constant. As a result of these preliminary actions, the Air Force submitted to DMMB a recommendation "to stock list an antacid comparable to Titralac tablets."

DMMB advised the Army and Navy of the Air Force action, and requested service positions.

Working from the Air Force recommendation, Army and Navy personnel reviewed their own reports, consulted their specialists, concurred with the Air Force and the item was standardized. These reviews include consideration of such data as local purchase statistics, professional needs and uses, patient acceptance, comparison with items already stock listed, and an evaluation of known sources of supply.

ESSENTIAL CHARACTERISTICS

Since the Air Force request named only the one commercial product, it was necessary for DMMB to request Riker Laboratories for detailed information on Titralac. Riker advised that the product was patented, but agreed to provide that information—physical and chemical characteristics, test protocols, clinical and stability studies—which specifically identify the item produced by that manufacturer.

The board used these data in the preparation of tentative essential characteristics for calcium carbonate and aminoacetic acid tablets. The essential characteristics (or EC's) are defined as those mandatory qualities required of an item to accomplish a specific professional, therapeutic, technical, or military purpose. For drugs, they include, but are not limited to a description of the item, and its application or use; components of the formula, when appropriate; quantification, as required; unit of issue, type of container, package size, and any special packaging instructions; and labeling requirements, identification data, and necessary instructions for use.

Initial proposals for type classification on an item are recorded on a "coordination worksheet for medical items pending adoption" (DMMB form 1, Exh. 1).[1] DMMB distributed this form 1 concurrently to the services and to DPSC. Comments were solicited from all addresses. The services annotated the form 1 with their initial, and 12 months replenishment requirements.

Within DPSC, the form was reviewed in the technical and supply operations divisions of the medical directorate to hasten availability of the drug through the DOD wholesale distribution depots. Having

[1] See exhibits beginning at p. 7588.