THE UNITED STATES PHARMACOPEIA

In many instances, the so-called "additional requirements" are trivial with respect to drug standardization, whatever their merit may be otherwise. Examples are the color of Ethinyl Estradiol Tablets and palatability of Meclizine Hydrochloride Tablets (page 17). These attributes may be of utility and importance to the consumer, but they are not properly subjects for strict USP standard-setting.

An example of a superfluous "additional requirement" is the test for loss on drying for Meclizine Hydrochloride Tablets (page 17). The Department of Defense states that this test is intended "to assure the stability of the product, in that excessive moisture may cause deterioration." To our knowledge, USP has received no scientific data to support this statement from either the Department of Defense or regulatory agencies, or from users or manufacturers of the product. In the absence of such supporting information, we would see no reason for adopting the proposed standard.

An "additional requirement" for Mannitol USP (page 38) is that it shall be free of boron because "the item is used in water chemistry control." USP is concerned with setting standards for articles to be utilized as drugs, not for any other purposes.

In my opinion, the documents submitted to you contain but few authentic examples of definitive product specifications that exceed present USP standards.

Sincerely yours,

Daniel Banes, Ph.D.

DB/ps