THE UNITED STATES PHARMACOPEIA

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Mr. Benjamin Gordon
Staff Economist, Senate Select
Committee on Small Business
424 Russell Senate Office Building
Washington, D. C. 20510

Dear Mr. Gordon:

In response to your telephone call of 27 February 1974, I have perused the 67-page compilation on "Additional Requirements" submitted by the Department of Defense to the Subcommittee on Monopoly of the Senate Select Committee on Small Business. These documents, supplementing a similar list previously transmitted to you, comprise a catalog of about 500 drug products for which the Department of Defense is said to "develop definitive product specifications which often exceed official or commercial standards."

When I testified before the Subcommittee on Monopoly, I stated that in those few instances where the Department of Defense specifications have been considered scientifically significant and have served to strengthen the standards for a drug product, the United States Pharmacopeia has moved to adopt the modifications. In my testimony, I cited actual examples to illustrate that statement. The same observation holds for the supplementary listing now before us. It contains about 200 USP articles. Except for five or six articles, none of the so-called "definitive product specifications which exceed official standards" can be considered suitable candidates for adoption in the United States Pharmacopeia. From the standpoint of USP, the others are either irrelevant, trivial or superfluous.

The most frequently occurring entries under "Additional Requirements" are the phrases: "Classification of Defects" and "maximum unrefrigerated shipping time for items requiring refrigeration." Neither is germane to USP standard-setting.

Another commonly encountered "requirement" is "Free from sediment" for certain fluid drugs (e.g. Cinnamon Oil on page 1, Diphenhydramine Hydrochloride Elixir on page 2, etc.) which is said "to assure best production procedures and controls are utilized consistent with good manufacturing practices." This "additional requirement" is redundant; drugs in solutions by definition should be free from solids of all kinds, including sediments.