Drug Standards

In the United States, the two most important official compendia of drug standards and specifications are the U.S. Pharmacopeia (USP) and the National Formulary (NF). Both have long and distinguished histories, and are highly regarded by physicians and scientists.

Although both publications have clearly stated that they cannot guarantee it, their standards and specifications have been widely presumed to assure the clinical equivalency of chemical equivalents.

The recent finding that some chemical equivalents are not biologically equivalent, even though they conform to existing USP and NF standards, has shown that certain of these standards may require revision.

During the past year, representatives of both USP and NF have been cooperating closely with the Task Force to meet this challenge. It is expected that existing specifications will be tightened where indicated and possible, and that these modifications will be incorporated in the revised USP and NF editions now in preparation.

The Task Force commends the U.S. Pharmacopeia and the National Formulary for their prompt and responsible approach to the problem of clinical equivalency.