

When the American Pharmaceutical Association (APhA) was organized in 1852, the only authoritative and recognized book of drug standards available was the third revision of the USP. To serve as a therapeutic guide to the medical profession, its scope, then as now, was restricted to drugs of established therapeutic merit. Because of strict selectivity, many drugs and formulas that were accepted and used by the medical profession were not granted admission to early revisions of the USP. As a type of protest, and in keeping with the original objectives of the APhA to standardize drugs and formulas, certain pharmacists, with the sanction of their national organization, prepared a formulary containing many of the popular drugs and formulas denied admission to the USP. The first edition was published in 1888 under the title *National Formulary of Unofficial Preparations* (3). The designation “unofficial preparations” reflected the protest mood of the authors, since the USP had earlier adopted the term “official” as applying to the drugs for which it provided standards. The title was changed to *National Formulary* (NF) on June 30, 1906, when President Theodore Roosevelt signed into law the first federal Pure Food and Drug Act, designating both the USP and NF as establishing legal standards for medicinal and pharmaceutical substances. Thus the two publications became official compendia. Among other things, the law required that whenever the designation USP or NF was used or implied on drug labeling, the products must conform to the physical and chemical standards set forth in the compendium monograph.

The early editions of the NF served mainly as a convenience to practicing pharmacists by providing uniform names of drugs and preparations and working directions for the small-scale manufacture of popular pharmaceutical preparations prescribed by physicians. Before 1940, the NF, like the USP, was revised every 10 years. After that date, new editions appeared every 5 years, with supplements issued periodically as necessary.

In 1975, the United States Pharmacopeial Convention, Inc. purchased the NF, unifying the official compendia and providing the mechanism for a single national compendium.

Today, the United States Pharmacopeia-National Formulary (USP-NF) is continuously revised. Revisions are available annually in hard copy and as online editions, including twice-yearly supplements and update notices on the USP Web site. Monographs for drug substances, dietary supplements, dosage forms, and compounded preparations are contained in the USP sections of the combined compendium whereas monographs for pharmaceutical excipients are contained in the NF section.

A *Spanish* edition of the USP-NF was introduced in 2006. Presently, USP standards are used in more than 140 countries worldwide.

The standards advanced by the USP and the NF are put to active use by all members of the health care industry who share the responsibility and enjoy the public's trust for ensuring the availability of quality drugs and pharmaceutical products and preparations. The term “products” is now generally used to refer to manufactured drugs and “preparations” to compounded drugs. The USP-NF is used by pharmacists, physicians, dentists, veterinarians, nurses, producers, and suppliers of bulk chemicals for use in drug production; large and small manufacturers of pharmaceutical products; drug procurement officers of various private and public health agencies and institutions; drug regulatory and enforcement agencies; and others.

USP and NF Monographs

The USP and NF adopt standards for drug substances, pharmaceutical ingredients, and dosage forms reflecting the best in the current practices of medicine and pharmacy and provide suitable tests and assay procedures for demonstrating compliance with these standards. In fulfilling this function, the compendia become legal documents, every statement of which must be of a high degree of clarity and specificity.

In the United States, a drug with a name recognized in the USP-NF must comply with compendial identity standards or be deemed adulterated, misbranded, or both. To avoid being deemed adulterated, such drugs also must comply with compendial standards for