National Formulary XIV

NATIONAL FORMULARY XIV

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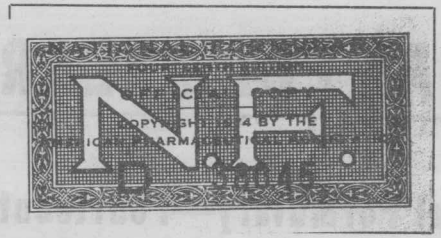

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PREFACE

"The ready availability of the currently effective editions of the compendia on the premises of a pharmacy can contribute in a very material manner to compliance by the pharmacist with his legal and professional obligations in the storage, packaging, labeling, and dispensing of quality drugs ...." This quotation is but one of nine statements on the importance of the National Formulary and United States Pharmacopeia included in a resolution encouraging the use and acceptance of the official compendia and urging renewed professional support adopted in 1970 by the House of Delegates of the American Pharmaceutical Association.

The official compendia set forth standards of identity, strength, quality, purity, packaging, storage, and labeling of drug and related articles recognized on the basis of therapeutic value. In the broad view, pharmacy fulfills an important professional responsibility through the role that has been entrusted to it in the development of these standards. Because of the characteristic of contemporary pharmaceutical service which results in pharmacists relying heavily on pharmaceutical preparations prefabricated by manufacturers as the source of drugs to be dispensed on prescription, it is relatively easy to overlook the pharmacist's fundamental responsibility—both from the standpoint of his or her professional position and from a legal standpoint—for the identity, strength, quality, and purity of all prescription medication dispensed, regardless of the type of medication prescribed.

Moreover, a primary objective of official compendium standards is to ensure uniformity of drug products from lot to lot and from manufacturer to manufacturer. This kind of uniformity constitutes a key component in ensuring brand-to-brand quality, thereby making brand interchange by the pharmacist and the exercise of the professional judgment in drug product selection for which he or she is qualified a feasible reality.

However, of greatest direct, practical importance to pharmacists—as well as to the various state regulatory agencies whose efforts are concerned principally with drug distribution—is that official compendia standards encompass more than identity, strength, quality, and purity. Among the standards promulgated by NF and USP are those intended to protect drug products from deterioration, thereby ensuring continuing effectiveness of the medication. This is achieved generally by specifying that individual articles be packaged in particular types of containers (well-closed, tight, light resistant, *etc.*) where necessary, by specifying storage conditions (refrigerator, cold place, controlled room temperature, *etc.*), and through labeling and other standards as well.

In contrast to other official compendia specifications, packaging and storage standards apply to the pharmacist in dispensing the drug product to the patient as well as to the manufacturer who prepares and distributes the product. These standards are helpful not only in meeting legal obligations, but also in providing professional guidance to patients on proper packaging and storage of drug articles. Pharmacists may obtain information on packaging and storage standards for specific drugs by referring to the official monographs in their NF and USP, which are the only authoritative sources of information pertaining to these and other compendial standards.

NF–USP Consolidation

Through intensive negotiations in mid-1974, agreement was reached between the American Pharmaceutical Association (acting as publisher of the National Formulary) and the United States Pharmacopeial Convention, Inc., (USPC) on the single most significant