THE
NATIONAL FORMULARY
TENTH EDITION
NATIONAL FORMULARY X

N. F. X

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PREFACE

The tenth edition of the National Formulary is the fourth to be published according to a plan adopted by the Council of the American Pharmaceutical Association in 1938 for the issuance of revisions at five-year intervals. This plan, together with a provision for the issuance of Interim Revision Announcements and Supplements, makes it possible to keep the National Formulary abreast of the rapid development of new drugs and to issue interim revisions promptly when needed. One Supplement to N. F. IX was issued in 1950 and one Interim Revision Announcement in 1952.

During the course of the revision of the ninth edition of the National Formulary, leading to the publication of this edition, substantial changes in the content of the text were made. Many of the monographs on drugs and dosage forms appearing in the ninth edition have been continued in the tenth. A total of 242 of the 717 drug items official in N. F. IX, however, were not admitted to N. F. X. Titles and standards for 259 drugs, for which official standards would not otherwise be provided were added to N. F. X during the recently completed revision program. In the process of revision, many individual specifications for strength, quality, purity, and identity were revised and materially improved.

Several new features were added to N. F. X. Among these are specifications for the disintegration time of coated, buccal, and sublingual tablets; weight variation standards for the content of dry-filled capsules; and for solubility of hypodermic tablets. Through the efforts of a joint U. S. P. and N. F. Panel on Sterility Requirements, the general chapters on injections and sterility tests were revised and a new chapter on general sterilization procedures was prepared. A new section on general information has been added to N. F. X. This section includes specifications for prescription balances, weights, measuring devices; formulas for clinical laboratory reagents; a selected list of drugs and formulas for preparations used by chiropodists; basic information relating to dyes for use in coloring pharmaceutical preparations; a table comparing the names and standards of strength of drugs covered in the International Pharmacopoeia with those appearing in N. F. X; and a description of general sterilization procedures.

The section on clinical laboratory reagents and the table of optical crystallographic characteristics of N. F. medicinal chemicals have undergone considerable revision and have been transferred to the general information section.

Authority—The National Formulary is revised by the Committee on National Formulary under the direct authority and supervision of the Council of the American Pharmaceutical Association, as provided in Chapter IX, Article V, of the By-Laws of the Association (as of 1951), which follows:

"Article V. *Committee on National Formulary.* The Committee on National Formulary shall consist of a chairman elected by the Council for a term of five years and ten members elected by the Council, two to serve for a term of one, two, three, four and five years, respectively, and the Director of the A. Ph. A. Laboratory who shall be a member of the Committee, *ex-officio;* each vacancy occurring other than from expiration of term shall be filled by election for the unexpired term. The Committee shall elect a Vice-Chairman and a Secretary from its own membership. This Committee shall serve as an executive committee of revision of the National Formulary; the members shall serve as chairmen of the subcommittees of the Committee and shall nominate to the Council additional participating members of each subcommittee to the number of not more than five, at least one member of each subcommittee to be a retail pharmacist. The Committee on National Formulary shall report annually, or as often as required, to the Council."

N. F. Scope—The general principles followed by the Committee on National Formulary in the compilation of the tenth edition have not been changed materially from previous editions. The purpose continues to be the establishment and publication of official standards for drugs. The admission of drugs to this edition has been based on therapeutic value and upon the extent of use. Therapeutic value, as a criterion for admission to N. F. X was given greater priority than heretofore by the Committee on National Formulary in reaching final decisions on scope.

The Significance and Function of the National Formulary—The National Formulary renders a distinct service to pharmacists and pharmaceutical manufacturers by providing specifications for the procurement of drugs used in dispensing, prescription compounding, and manufacturing, and supplying formulas and working directions for the preparation of dosage forms. It provides standards for use by state and federal food and drug law administration officials in their enforcement programs, thus simplifying legal procedures. The activities and functions of the National Formulary constitute an important service to the medical profession and to the public. In the beginning, the National Formulary served only as a convenience to practicing pharmacists by providing uniform names, uniform formulas, and working

directions for the small-scale manufacture of pharmaceutical preparations frequently prescribed by physicians.

Until 1906, when it was designated as one of the two official compendia by the terms of the Federal Food and Drugs Law, the function and significance of the National Formulary remained unchanged. The provisions inherent in the 1906 law and the Federal Food, Drug, and Cosmetic Act of 1938, however, have increased the obligation of those responsible for the revision of the National Formulary, and have added greatly to its significance.

The position of the National Formulary as a book of legal standards for drugs is made clear by the authority conferred upon it by the 1938 Federal Food, Drug, and Cosmetic Act. Section 501(b) of this statute requires that drugs purporting to be those listed in the National Formulary must conform to the standards of strength, quality, and purity prescribed by that compendium. All determinations of these standards must be made in accordance with the methods described in the text. Variations from these standards are permitted only when certain labeling requirements of the Act indicating the nature of the variation are met.

The same section of the Act authorizes the U. S. Secretary of Health, Education, and Welfare to prescribe tests where none have been provided or where those described are believed to be insufficient. Before the Secretary can take such action, however, he must first call to the attention of those responsible for the revision of the National Formulary the need for additional or more adequate tests. He may then proceed only after a reasonable time has elapsed, and the Committee on National Formulary has failed to provide adequate tests or methods of assay. Thus, while considerable authority to promulgate standards is conferred by the Act upon the American Pharmaceutical Association and its Committee on National Formulary, adequate checks and safeguards against omissions, arbitrary, or scientifically unsound specifications are also provided.

Style—The arrangement of monographs on drugs is essentially the same as in N. F. IX. Latin titles have in most instances been discontinued. Monographs are arranged in alphabetical sequence so that a monograph on a basic drug is followed by monographs on its official preparations. In order to facilitate the use of this arrangement, a marginal index is included. All doses are expressed in the metric system of weights or measures, printed in boldface type and followed in parentheses by the approximate equivalent in the apothecaries' system in less

prominent type. A statement of the best-known pharmacologic action, designated as *Category* has been added to each monograph.

Publicity—During the period since the publication of N. F. IX information on revision plans has been made available through the *Journal of the American Pharmaceutical Association* and *Drug Standards*. Galley proof and page proof for the text of the National Formulary were widely distributed to representatives of all branches of the pharmaceutical profession and interested government agencies. An open conference on N. F. X standards was held by the Committee on National Formulary in Washington, D. C. on November 10, 1954. During this open conference an opportunity was offered for the public presentation of criticisms and suggestions relating to all proposed N. F. X standards. Through the use of these media many helpful suggestions and recommendations were received and adopted by the Committee on National Formulary.

Coupon—A coupon will be found on the back of the title page as in previous editions of the National Formulary, bearing the number of the copy and the following words: "National Formulary, Tenth Edition, Official Copy. Copyright, 1955, by the American Pharmaceutical Association." This coupon serves to identify an official copy of the National Formulary and should not be removed.

Official Date—The Council of the American Pharmaceutical Association has determined the date on which N. F. X is to supersede the ninth edition of the National Formulary. This date is December 15, 1955.

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Assistance—The Committee on National Formulary has had the benefit of valuable cooperation from many who are not members of the Committee, but who have voluntarily given of their time and knowledge in supplying information upon which many decisions have been based. Special appreciation is expressed for their services. The voluntary character of a large proportion of the work of revision has been supplemented by the services of the staff members of the American Pharmaceutical Association Laboratory. The Chairman wishes to acknowledge gratefully the assistance of Dr. Samuel W. Goldstein, Director of the American Pharmaceutical Association Laboratory, for the development of specifications for newly admitted drugs, for writing the preliminary drafts of many of the monographs, and for his sustained cooperation during the entire publication period.

The Chairman also acknowledges with gratitude the constant encouragement, advice, and assistance rendered during the revision period by the Council, the Committee on Publications, and by Dr. Robert P. Fischelis, Secretary and General Manager of the American Pharmaceutical Association. The sympathetic understanding by Dr. Fischelis of the many complex revision and publication problems encountered is particularly appreciated.

Valuable advice and assistance were furnished by several departments of the government and particularly by the Food and Drug Administration, and the National Institutes of Health, of the Department of Health, Education and Welfare, and the U.S. Bureau of Standards.

The assistance rendered by the Combined Contact Committee of the American Drug Manufacturers Association and the American Pharmaceutical Manufacturers' Association was particularly outstanding. Through the cooperation of numerous collaborative subcommittees, many general specifications such as those for the disintegration time of tablets and weight variation standards for the content of dry-filled capsules were devised. Other specifications for basic drugs and dosage forms such as the tocopherols and aspirin, phenacetin, and caffeine capsules and tablets were also developed through extensive collaborative studies by subcommittees of the Contact Committee.

Several individual pharmaceutical manufacturers also supplied the

Committee with background information upon which specifications for newly admitted drugs have been based.

Members of the Scientific Section of the Essential Oil Association of U. S. A. have contributed to the revision of the monographs on essential oils and aromatic chemicals. Specifications for reagent chemicals have been adapted from those established by the Committee on Analytical Reagents of the American Chemical Society and published in *Reagent Chemicals ACS Specifications 1950.* In the development of monographs for several of the newly admitted drugs, we have drawn freely on specifications prepared by the Council on Pharmacy and Chemistry of the American Medical Association and published in *Tests and Standards for New and Nonofficial Remedies 1953.* The assistance of the American Dental Association and the use of information in *Accepted Dental Remedies* is also acknowledged with thanks. Information on biological stains, furnished by the Biological Stain Commission has been utilized in the specifications for dyes used as biological stains.

Through the 1950–55 revision period, information has been freely exchanged between the United States Pharmacopeia and the National Formulary revision committees. The cordial cooperation of Dr. Lloyd C. Miller, Director of Revision of the United States Pharmacopeia, has been particularly outstanding and is a source of gratification. Through his cooperation, the several features of the National Formulary, which the Pharmacopeia and the National Formulary have in common, such as the General Notices and the Section on General Tests, Processes, and Apparatus, have been kept in substantial agreement with comparable sections in the United States Pharmacopeia.

Many individuals other than members of the Committee on National Formulary have contributed to this edition by serving as members of special advisory committees and by furnishing background information and advice on which many of the specifications in drug monographs were based. A list of those whose names do not appear as members of subcommittees or special advisory committees, but who rendered outstanding assistance appears on page ix. The Chairman has been assisted most competently throughout the entire revision program by Miss Beatrice Lyons whose close attention to a myriad of details has avoided many errors that might otherwise have occurred in this edition. For her loyal and faithful assistance he is deeply grateful.

HISTORY OF THE NATIONAL FORMULARY*

FORMULARIES and pharmacopeias from very early times have had an important and significant influence upon the establishment and observance of drug standards. The early standards for drugs, however, were not at all comparable to those of today. That could not be expected. Standards for drugs of any period are always limited by the stage of development of the collateral sciences upon which they depend. The development of new standards for established drugs, and the discovery of new drugs, have closely paralleled the advancements in science. On the other hand, the search for a better knowledge of drugs has frequently contributed to the advance of science in general, and to pharmacy, chemistry, and pharmacology in particular.

Early pharmacopeias and formularies could do little more than provide uniformity of titles for botanical drugs and the few available medicinal chemicals, methods for preparation of the latter, and uniformity of formulas for dosage forms of these drugs.

The events leading to the publication of the first edition of the National Formulary and its progress since its appearance in 1888 illustrate a phase in the evolution of drug standards. When the American Pharmaceutical Association was organized in 1852, the only authoritative and generally recognized book of drug standards available was the third revision of the United States Pharmacopeia. It had been started in 1820 by physicians to serve as "a therapeutic guide to the medical profession." As such, its scope, then as now, was restricted to drugs selected by representatives of the medical profession, and believed by them to possess the greatest therapeutic merit. This selectivity has always prevented inclusion by the United States Pharmacopeia of a large number of drugs which, judged by the extent to which they are prescribed by physicians, may possess useful therapeutic properties. This pharmacopeial selectivity is largely responsible for the origin and development of the National Formulary, and is one of the main reasons there are two official drug compendia in the United States today.

The idea of a National Formulary for use in the United States is nearly as old as the American Pharmaceutical Association. This asso-

* For a more detailed history of previous editions of the National Formulary see N. F. VIII, pages xiv to xxvii.

ciation of pharmacists organized in 1852 included among its original objectives the following:

"(a) To improve and regulate the drug market by preventing the importation of inferior, adulterated or deteriorated drugs and by detecting and exposing home adulterations. (b) To improve the science and art of pharmacy by diffusing scientific knowledge among pharmacists and druggists, fostering pharmaceutical literature, developing talent, stimulating discovery and invention, encouraging home production and manufacture in the several departments of the drug business. (c) To uphold standards of authority in the education, theory, and practice of pharmacy. (d) To create and maintain a standard of professional honesty equal to the amount of our professional knowledge with a view to the highest good and greatest protection to the public."

One means of partially activating these objectives was to promote the standardization of names and formulas for extensively used dosage forms of drugs not described in the U. S. Pharmacopeia. It is therefore not surprising to find that as early as 1856 an American Pharmaceutical Association committee was appointed to develop plans for the compilation of standards for dosage forms not included in the United States Pharmacopeia of that period. During several ensuing years such a committee was continued, but plans for a formulary entirely acceptable to the Association were not presented. In the meantime, a book on elixirs by John Uri Lloyd, and the New York and Brooklyn Formulary for local use were published in 1883. Pharmaceutical interest in these books stimulated the Association to intensify its efforts to produce a formulary, and in 1888 the first edition of the National Formulary was published under the title "National Formulary of Unofficial Preparations."

The designation "Unofficial Preparations" in the title was used because the Pharmacopeia had earlier adopted the term "official" as applying to the drugs for which it provided standards. The title of the publication was changed to "National Formulary" when, by the terms of the Federal Food and Drugs Law of 1906, both the United States Pharmacopeia and the National Formulary were designated as official compendia.

The First Three Editions of the National Formulary

The first edition of the National Formulary was a book of formulas for widely used dosage forms of that period such as elixirs, emulsions,