

1995

USP 23

NF 18

THE UNITED STATES PHARMACOPEIA

THE NATIONAL FORMULARY

By authority of the United States Pharmacopeial Convention, Inc., meeting at Washington, D.C., March 8-10, 1990. Prepared by the Committee of Revision and published by the Board of Trustees

Official from January 1, 1995



UNITED STATES PHARMACOPEIAL CONVENTION, INC.
12601 Twinbrook Parkway, Rockville, MD 20852

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Articles of Incorporation

The United States Pharmacopoeial Convention of May 1900, directed the Board of Trustees to take out articles of incorporation for the Convention under the laws of the District of Columbia. While the Convention had appointed certain of its officers to sign the articles, some changes were necessary because the

laws aforesaid require that a majority of the Incorporators be residents of the District of Columbia.

These preliminaries having been arranged, the following certificate of incorporation was drawn up, signed, and recorded, finally, on the eleventh day of July, 1900:

Certificate of Incorporation

This is to certify that we, whose names are hereunto subscribed, citizens of the United States, of full age, and a majority citizens of the District of Columbia, do associate ourselves together pursuant to the provisions of sections 545-552 inclusive of the Revised Statutes of the United States relating to the District of Columbia and of the Act of Congress to amend the same, approved the twenty-third day of April 1884, under the corporate name of The United States Pharmacopoeial Convention.

This Association is organized for a period of nine hundred and ninety-nine years.

The particular objects and business of this Association are the encouragement and promotion of the science and art of medicine and pharmacy by selecting by research and experiment and other proper methods and by naming such materials as may be properly used as medicines and drugs with formulas for their preparation; by establishing one uniform standard and guide for the use of those engaged in the practice of medicine and pharmacy in the United States whereby the identity, strength, and purity of all such medicines and drugs may be accurately determined, and for other like and similar purposes; and by printing and distributing at suitable intervals such formulas and the results of such and similar selections, names and determinations among the members of this Association, pharmacists, and physicians generally in the United States and others interested in pharmacy and medicine.

The management and control of the affairs, funds, and property of this Association for the first year of its existence shall be vested in a Board of Trustees consisting of the seven following persons:

ALBERT E. EBERT.
SAMUEL A. D. SHEPPARD.
WILLIAM S. THOMPSON.
CHARLES E. DOHME.

GEORGE W. SLOAN.
HORATIO C. WOOD.
CHARLES RICE.

In testimony whereof we have hereunto set our hands and affixed our seals this seventh day of July, 1900.

WILLIAM S. THOMPSON. [SEAL]
G. LLOYD MAGRUDER. [SEAL]
JOHN T. WINTER. [SEAL]
THOMAS C. SMITH. [SEAL]

MURRAY G. MOTTER. [SEAL]
WILLIAM M. MEW. [SEAL]
FRANK M. CRISWELL. [SEAL]

Constitution and Bylaws

The United States Pharmacopeial Convention

*Under which USP 23 and NF 18 were prepared
As revised by the Convention at its Quinquennial meeting,
March 8–10, 1990*

CONSTITUTION

Article I—Name and Objects

Section 1. The corporate name of this corporation shall be “The United States Pharmacopoeial Convention,” hereinafter referred to in this Constitution as the Pharmacopeial Convention.

The alternative spelling, “Pharmacopeial,” also shall be considered as official.

Section 2. Its objects shall be those declared in its Certificate of Incorporation, and include (a) the revision and publication of the *Pharmacopeia of the United States of America* and the *National Formulary*, also referred to as the *United States Pharmacopeia* and as the *USP* and as the *NF*, respectively, and of the *Supplements* thereto; and (b) the publication regularly or at suitable times of other information of related scientific purpose. The term authorized shall be applied to such information when it has been prepared in accordance with the rules and procedures adopted by the Committee of Revision, or otherwise by direction of the Board of Trustees. Approval of the Board of Trustees shall be required for publication in either case.

Section 3. The *Pharmacopeia of the United States of America* and the *National Formulary*, together with their *Supplements*, are published by and issued under the authority of the Pharmacopeial Convention; they are prepared and regularly revised entirely or in part by a committee or committees of representative medical and pharmaceutical experts and other appropriately qualified individuals; their primary purpose is to provide authoritative standards and specifications for materials and substances and their preparations that are used in the practice of the healing arts; they establish titles, definitions, descriptions, and standards for identity, quality, strength, purity, packaging, and labeling, and also, where practicable, bioavailability, stability, procedures for proper handling and storage, and methods for their examination and formulas for their manufacture or preparation.

Article II—Membership

Section 1. The members of the Pharmacopeial Convention shall consist of: accredited delegates representing the following educational institutions, professional and scientific organizations, and designated divisions of the federal government, hereafter designated as eligible organizations, and others as herein provided.

In this Constitution and Bylaws “state” or “United States” includes each of the several states, the District of Columbia, the Commonwealth of Puerto Rico, and all territorial possessions of the United States of America.

(a) Colleges and schools of medicine in the United States with programs accredited by the Liaison Committee on Medical Education sponsored by the Association of American Medical Colleges and by the Council on Medical Education of the American Medical Association; colleges and schools of pharmacy in the United States with programs accredited by the American Council on Pharmaceutical Education; state medical associations or state medical societies, which are constituents of the American Medical Association; and state pharmaceutical associations or state pharmaceutical societies, which are entitled to voting delegates in the House of Delegates of the American Pharmaceutical Association.

(b) The American Association of Pharmaceutical Scientists, the American Chemical Society, the American Dental Association, the American Hospital Association, the American Medical Association, the American Nurses Association, the American Pharmaceutical Association, the American Society for Clinical Pharmacology and Therapeutics, the American Society of Hospital Pharmacists, the American Society for Pharmacology and Experimental Therapeutics, the American Society for Quality Control, the American Society of Consultant Pharmacists, the American Veterinary Medical Association, the Association of Food and Drug Officials, the Association of Official Analytical Chemists, the Chemical Manufacturers Association, the Cosmetic, Toiletry, and Fragrance Association, the Drug Information Association, the Generic Pharmaceutical Industry Association, the Health Industry Manufacturers Association, the National Association of Boards of Pharmacy, the National Association of Chain Drug Stores, the National Association of Retail Druggists, the National Wholesale Druggists’ Association, the Nonprescription Drug Manufacturers Association, the Parenteral Drug Association, and the Pharmaceutical Manufacturers Association; or the successors thereto.

(c) The Bureau of Medicine and Surgery, United States Navy; the Department of Medicine and Surgery, the Department of Veterans Affairs; the Food and Drug Administration; the Health Care Financing Administration; the National Institute of Standards and Technology; the Office of the Surgeon General, United States Air Force; the Office of the Surgeon General, United States Army; the Office of the Surgeon General, United States Public Health Service; the Office of the Secretary of the Department of Health and Human Services; and the Office of the President of the United States to represent Consumer Affairs; or the successors thereto.

(d) An individual who has been appointed to be a delegate by one of not more than five organizations that have been designated as eligible organizations by the Board of Trustees. Such designation by the Board of Trustees shall be effective until the next stated meeting.

(e) The Officers, the Board of Trustees, and the Chairmen of Committees directed to report at a stated meeting, serving by authority of the preceding stated Pharmacopeial Convention or the Constitution and Bylaws, also shall be members, ex officio, of the Pharmacopeial Convention.

(f) Not more than twenty members-at-large, selected by the Board of Trustees for their special competence in relation to the administrative or scientific needs of the Pharmacopeia, also shall be members of the Pharmacopeial Convention until the next stated meeting, with such membership to begin upon the individual's acceptance.

(g) Not more than five members-at-large selected by the Board of Trustees to serve as public members also shall be members of the Pharmacopeial Convention until the next stated meeting, with such membership to begin upon the individual's acceptance.

(h) Not more than five members-at-large selected by the Board of Trustees to represent nations, other than the United States, that give official recognition to the standards of the USP or the NF also shall be members of the Pharmacopeial Convention until the next stated meeting, with such membership to begin upon the individual's acceptance.

(i) Not more than ten members-at-large selected by the Board of Trustees to represent international organizations or foreign pharmacopeial bodies also shall be members of the Pharmacopeial Convention until the next stated meeting, with such membership to begin upon the individual's acceptance.

(j) Nominees for elective offices, selected in accordance with Chapter IX, Sections 2 and 3, of the Bylaws, shall be members of the Pharmacopeial Convention for the stated meeting when their names are presented as nominees in accordance with Chapter IV, Section 13 (h), of the Bylaws, whether present or not.

Section 2. Each eligible organization entitled to representation in the Pharmacopeial Convention, as provided for in Article II, Section 1, of this Constitution shall elect or appoint in such manner as it may determine, one delegate and one alternate delegate. One of these shall be accredited and seated as a member of the Pharmacopeial Convention, as provided in the Bylaws.

Section 3. Each delegate and alternate delegate, at the time of his or her election or appointment, and each member of the Convention, during his or her membership, except those named under Article II, Sections 1 (f) and (g), shall be an officer or a member of the academic staff of the educational institution; an officer, active member, or employee of the organization; or an employee of the division of the federal government that he or she represents.

Section 4. Honorary Members. By unanimous vote the Board of Trustees may elect honorary members to the Convention in recognition of their distinguished contribution to drug standardization, drug information, the sciences of medicine and pharmacy, and the public health. Each honorary member shall have the rights, privileges, and duties prescribed by the Constitution and Bylaws and defined by the Board of Trustees except the right to vote, to hold office, or to otherwise determine the policy and administration of the Convention.

Article III—Officers

Section 1. The officers of the Pharmacopeial Convention shall be a President and a Vice-President, each of whom, at the time of his or her election, shall be a member of the Pharmacopeial Convention; a Past President; a Treasurer; and a Secretary. The President, the Vice-President, and the Treasurer shall be elected by ballot at each stated meeting. The Committee of Tellers shall report to the President the number of votes cast for each nominee, and the President shall announce to the Convention the winner(s) in each office or position without disclosing the number of votes cast or the number received by each nominee. However, any nominee may publicly or privately obtain this information with regard to his or her own election and the election of others seeking election to the same position or classification, and, in such event, to the degree it is necessary to do so in order that the Convention

may rule upon the propriety of the election, the votes cast may be disclosed publicly.

The Secretary of the Board of Trustees shall act as Secretary of the Pharmacopeial Convention.

Section 2. Vacancies in these offices shall be filled as provided in the Bylaws.

Article IV—Board of Trustees

The members of the Pharmacopeial Convention shall elect a Board of Trustees from the members of the Convention at each stated meeting, as provided in the Bylaws. The Committee of Tellers shall report to the President the number of votes cast for each nominee, and the President shall announce to the Convention the winner(s) in each office or position without disclosing the number of votes cast or the number received by each nominee. However, any nominee may publicly or privately obtain this information with regard to his or her own election and the election of others seeking election to the same position or classification, and, in such event, to the degree it is necessary to do so in order that the Convention may rule upon the propriety of the election, the votes cast may be disclosed publicly.

Article V—The General Committee of Revision

The members of the Pharmacopeial Convention shall elect a General Committee of Revision at each stated meeting, as provided in the Bylaws. The members of the Committee shall act as the Committee until its successor committee shall have been elected and shall have assumed the duties of the Committee.

Article VI—Meetings

Section 1. The stated meetings of the Pharmacopeial Convention shall be held in the United States at five-year intervals, beginning in 1980. The Board of Trustees is authorized to determine the day within the year and the place of the meeting.

Section 2. The President shall call a special meeting upon the written request of not fewer than fifty members of the Pharmacopeial Convention.

Article VII—Quorum

At any session of a meeting of the Pharmacopeial Convention, one hundred members who are eligible to vote shall constitute a quorum.

Article VIII—Amendments

Section 1. Every proposition to amend this Constitution, except as hereinafter provided, shall be submitted to the Board of Trustees in writing, subscribed to by at least five members of the Pharmacopeial Convention, not later than one hundred and twenty days prior to a stated or a special meeting and, after review by the Board, shall be submitted, together with the Board's recommendation, not later than sixty days prior to a stated or a special meeting of the Pharmacopeial Convention, to the medical and pharmaceutical press, to those authorized to send delegates to the Pharmacopeial Convention, and to those persons who are authorized to attend the stated or a special meeting. Except as provided in Section 3, at the next ensuing meeting of the Pharmacopeial Convention, after the expiration of the said sixty days, upon receiving the affirmative votes of not less than three-fourths of the members present and voting, the proposition shall become a part of this Constitution.

Section 2. An amendment also may be proposed in writing by ten or more members at any session of a stated meeting except the final session. Such amendment shall be referred to the Board of Trustees, which shall report upon it at the next succeeding session when, upon receiving the affirmative votes of not less than seven-eighths of the members present and voting, it shall become a part of this Constitution.

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