

Supplement

3

Cumulative with First Two Supplements

USP XX

NF XV

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CORRECTIONS OF TEXT ON PAGES xi AND xiii OF USP XX

Advisory Panels to the Subcommittee on Scope and the Subcommittee on Posology and Related Information

In the listing under **Panel on Allergy, Immunology, and Connective Tissue Disease**, on page xi, change entry in line 5 to read:

STEVEN R. KAPLAN, M.D., Providence, R. I.

Members of the United States Pharmacopeial Convention and the Institutions and Organizations Represented, as of July 1, 1979

In the listing under **National Organizations—American Pharmaceutical Association**, on page xiii, change name to read:

EDWARD G. FELDMANN, Ph.D.,*

Constitution and Bylaws

THE UNITED STATES PHARMACOPEIAL CONVENTION

*As revised by the Convention
at its Quinquennial meeting, April 17–19, 1980*

CONSTITUTION

Article I—Name and Objects

Section 1. The corporate name of this corporation shall be “The United States Pharmacopeial 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, 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 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 Veterinary Medical Association, the Association of Food and Drug Officials, the Association of Official Analytical Chemists, the Chemical Manufacturers Association, the Cosmetic, Toiletry, and Fra-

grance Association, the Health Industry Manufacturers Association, the National Association of Chain Drug Stores, the National Association of Retail Druggists, the National Wholesale Druggists' Association, the Parenteral Drug Association, the Pharmaceutical Manufacturers Association, and The Proprietary Association; or the successors thereto.

(c) The Bureau of Medicine and Surgery, United States Navy; the Department of Medicine and Surgery, Veterans Administration; the Food and Drug Administration; the National Bureau of Standards; 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.

(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.

(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 and the NF also shall be members of the Pharmacopeial Convention until the next stated meeting.

(i) 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, 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 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.

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 4, 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.

Section 3. The Board of Trustees may at its discretion mail to the members of the Convention a proposition to amend or alter this Constitution. A period of sixty days shall be allowed for the submission of comments on the proposition. A summary of the comments shall accompany the mail ballot by which the vote of the member may be recorded and returned within ninety days of the date appearing on the ballot. Upon receiving the affirmative vote of seven-eighths of the members voting, with a total of not less than one hundred members voting, the proposition shall become a part of this Constitution.

BYLAWS

Chapter I—The President

Section 1. The President shall preside at all meetings of The United States Pharmacopeial Convention, hereinafter referred to in these Bylaws as the Pharmacopeial Convention. In the absence of the President or in the event of his or her inability to preside, the Vice-President, or in the absence or inability of both, a President pro tempore, to be appointed by the Board of Trustees, shall conduct the meeting.

Section 2. The presiding officer shall present an address at the stated meeting.

Section 3. The presiding officer shall have the right to call a member to the chair in order that he or she may take the floor in debate. The presiding officer shall not vote except in case of a tie, when he or she shall cast the deciding ballot.

Section 4. Not later than six months before the stated meeting of the Pharmacopeial Convention, the President shall appoint, subject to the advice and consent of the Board of Trustees, five members of the Convention as a Nominating Committee for Officers and Trustees, two of whom shall be members of the Board of Trustees. Of the members appointed from the Board of Trustees, one shall be representative of the pharmaceutical sciences and one shall be representative of the medical sciences.

Section 5. The President shall appoint all committees not otherwise provided for in these Bylaws.

Section 6. Not later than one year prior to the stated meeting of the Pharmacopeial Convention, the President, through the Secretary, shall mail a notice of the meeting and a request to prepare for the authorization or reauthorization of a delegate and an alternate delegate to each of those organizations eligible for representation under the Constitution. He or she shall mail a second notice of the meeting and the request for the authorization or reauthorization of a delegate and an alternate delegate not later than six months prior to the stated meeting. He or she shall also request medical, pharmaceutical, and other appropriate journals to publish the announcement of the said meeting. At suitable intervals the President, through the Secretary, may request by mail from an eligible organization, authorization or reauthorization of a delegate and alternate delegate.

Section 7. The President shall be a member, ex officio, of the Board of Trustees, and of all committees except the Committee of Revision.

Section 8. The President shall act as President until his or her successor shall have been elected and installed.

Section 9. In the event of a vacancy in the office of President, the Vice-President shall become President, or in the event the Vice-President is unable to serve, the Board of Trustees shall elect a President.

Chapter II—The Vice-President

Section 1. The Vice-President shall preside in the absence of the President or in the event of his or her inability to serve.

Section 2. The Vice-President shall become President in case of a vacancy in the office of President.

Section 3. The Vice-President shall be a member, ex officio, of the Board of Trustees.

Section 4. The Vice-President shall act as Vice-President until his or her successor shall have been elected and installed.

Section 5. A vacancy in the office of Vice-President shall be filled by the Board of Trustees.

Chapter III—The Past President

Section 1. The Past President shall be the immediate past president.

Section 2. The Past President shall be a member, ex officio, of the Board of Trustees.

Section 3. In the event the immediate past president is unable to serve as Past President, the office shall remain vacant.

Chapter IV—The Executive Director and Secretary

Section 1. The Executive Director shall be elected by the Board of Trustees as provided in Chapter VI, Section 18, of these Bylaws.

Section 2. The Executive Director shall be a member, ex officio, and Chairman of the General Committee of Revision and of the Executive Committee of Revision.

Section 3. The Executive Director shall organize the General Committee of Revision into not fewer than six Subcommittees, each to cover a specific phase of the work of revision. The rosters of the Subcommittees shall be subject to the advice and consent of the General Committee of Revision. The Executive Director shall appoint the Chairmen of the Subcommittees, subject to the approval of the respective Subcommittees. The Executive Director shall appoint all other committees required for the work of revision.

Section 4. The Executive Director shall have charge of the work of Revision, and shall cause to be prepared the final manuscript of The United States Pharmacopeia, the National Formulary, and other authorized publications, and any supplements thereto.

Section 5. The Executive Director and the Executive Committee of Revision shall consult on matters of general policy concerning the planning and executing of the revision of the Pharmacopeia, the National Formulary, and other authorized publications, and of supplements thereto.

Section 6. Whenever the occasion requires, the Executive Director shall certify in writing to the Board of Trustees that a new United States Pharmacopeia and new National Formulary, or a new supplement, has been completed, that each section of it has been approved by the Subcommittee to which its revision or preparation was assigned, and that the text in its entirety has been approved by the Executive Committee of Revision. The Executive Director shall also certify in writing to the Board of Trustees that an authorized publication or its supplement has been completed in accordance with existing rules and procedures.

Section 7. The Executive Director shall present an annual report to the Board of Trustees and also shall present a report of the General Committee of Revision at the stated meeting of the Pharmacopeial Convention.

Section 8. The Executive Director shall fill vacancies in the General Committee of Revision with the advice and consent of the General Committee of Revision and of the Board of Trustees.

Section 9. The Executive Director, with the advice and consent of the Board of Trustees, may appoint a committee composed of individuals from other nations who by law recognize or utilize the standards of the United States Pharmacopeia or the National Formulary to provide advice to the Committee of Revision.

Section 10. The Executive Director shall act as Executive Director until his or her successor shall have been elected and shall have assumed the duties of the office.

Section 11. In case of a vacancy in the position of Executive Director, the Chairman of the Board of Trustees shall appoint an Executive Director pro tempore, who shall serve until an Executive Director shall have been elected by the Board of Trustees.

Section 12. The Executive Director shall serve as the Secretary of the Board of Trustees and as Secretary of the Pharmacopeial Convention.

Section 13. Acting as the Secretary, the Executive Director shall:

(a) Keep the minutes of each meeting of the Pharmacopeial Convention and receive all reports, essays, and papers presented to the said meeting;

(b) Compile abstracts of the proceedings of the stated and special meetings and submit them to the Board of Trustees and, upon its order, arrange for their publication;

(c) At each stated meeting of the Pharmacopeial Convention, present a summary of the minutes of the preceding stated meeting;

(d) Present a report at the stated meeting of the Pharmacopeial Convention;

(e) Present to the Pharmacopeial Convention papers handed in for such purpose by the President;

(f) Record the ayes and nays when required;

(g) Notify the chairman and other members of each committee of their appointment, giving each member the name of the chairman of that committee and the names of the members and stating the business upon which the committee is to act;

(h) Immediately before the opening of the stated meeting of the Pharmacopeial Convention, post, in a conspicuous place in the meeting hall, a roll containing the names of the Officers of the Pharmacopeial Convention, the members of the Board of Trustees, the members of the General Committee of Revision, the Chairmen of Committees directed to report at the stated meeting, the persons selected by the Board of Trustees as members-at-large, the organizations designated as eligible organizations by the Board of Trustees, the persons selected by the Nominating Committee for Officers and Trustees as nominees for elected office, the delegates whose credentials have been approved by the Credentials Committee, and the order of business;

(i) During the stated meeting of the Pharmacopeial Convention, provide for each member two official ballots. One ballot shall contain the names of those nominated for President, for Vice-President, and for Treasurer of the Pharmacopeial Convention, and for the seven elective memberships on the Board of Trustees. A second ballot shall contain the names of those nominated for the General Committee of Revision, classified according to the outline of specific classifications of service prepared by the Executive Committee of Revision as provided in Chapter VII, Section 13, of these Bylaws, and designate the number to be elected in each classification, as provided in said outline;

(j) Deliver all reports, papers, and other documents of the Pharmacopeial Convention to the Board of Trustees;

(k) Issue such notices, announcements, and requests as provided for in Chapter I, Section 6, of these Bylaws, together with credential forms which shall be mailed with the second notice, and also mail the notices of special meetings as provided in Chapter XIII, Section 1, of these Bylaws;

(l) Submit to the Nominating Committee for the General Committee of Revision, not later than 90 days prior to the stated meeting of the Pharmacopeial Convention, all recommendations that have been submitted for membership on the General Committee of Revision;

(m) Acknowledge in writing the receipt of all resignations of membership and report them to the Board of Trustees;

(n) Serve as Secretary of all committees appointed by the President.

Section 14. In the absence of the Executive Director or in the event of his or her inability to serve as Secretary, the Chairman of the Board of Trustees shall appoint a Secretary pro tempore.

Section 15. The Executive Director shall act as Secretary until his or her successor shall have assumed the duties of the office.

Chapter V—The Treasurer

Section 1. The Treasurer shall receive all moneys coming from any source to the Pharmacopeial Convention and shall pay out moneys only on the authorization of and in accordance with the procedures adopted by the Board of Trustees.

Section 2. The Treasurer shall present annually to the Board of Trustees a complete financial statement and shall present at the stated meeting of the Pharmacopeial Convention a complete financial statement for the period since the preceding stated meeting.

The above statements of the Treasurer shall be audited by a certified public accountant.

Section 3. The Treasurer shall be a member, ex officio, of the Board of Trustees.

Section 4. During any temporary disability or absence of the Treasurer, an Acting Treasurer may be appointed by the Board of Trustees to serve in place of the Treasurer.

Section 5. The Treasurer shall act as Treasurer until his or her successor shall have been elected and installed.

Section 6. A vacancy in the office of Treasurer shall be filled by the Board of Trustees.

Chapter VI—The Board of Trustees

Section 1. The Board of Trustees shall consist of seven members of the Pharmacopeial Convention elected by plurality vote at the stated meeting; and the President, the Past President, the Vice-President, and the Treasurer, ex officio.

Of the seven elected members of the Board of Trustees, at least two shall be representative of the pharmaceutical sciences, and at least two shall be representative of the medical sciences. At least one of the elected members of the Board of Trustees shall be a public member.

The members of the Board of Trustees shall not be members of the General Committee of Revision.

No person shall be eligible to be an elected member of the Board of Trustees who, at the adjournment of the stated meeting, shall have served two successive terms as an elected member of the Board of Trustees.

Section 2. The officers of the Board of Trustees shall consist of a Chairman who shall be elected by a majority vote of the Board, and a Secretary. The Chairman of the Board of Trustees shall serve as a member, ex officio, of the Credentials Committee. The Secretary of the Board of Trustees need not be a member of the Board of Trustees or a member of the Pharmacopeial Convention. The Secretary of the Board of Trustees shall serve as Secretary of the Convention.

Section 3. The Board of Trustees shall have the right to transact business by correspondence. A motion by mail shall require no seconder.

Section 4. The Board of Trustees shall meet annually at such time and place as it shall determine. Special meetings of the Board of Trustees shall be called upon the written request of at least four members. The Chairman shall have the right to call a special meeting whenever he shall deem it necessary. Six members of the Board of Trustees shall constitute a quorum.

Section 5. Members of the Board of Trustees may participate in a special meeting of such Board by means of a telephone conference or similar communications equipment by means of which all persons participating in the meeting can hear each other at the same time, and participation by such means shall constitute presence in person at a meeting.

Section 6. No member of the Board of Trustees shall receive compensation for his services. Members of the Board of Trustees shall be reimbursed from the funds of the Pharmacopeial Convention for traveling and other necessary expenses that may be incurred by them in the performance of their duties.

Section 7. The Board of Trustees shall manage and control the affairs, funds, and property of the Pharmacopeial Convention, except as is herein otherwise provided.

The Board of Trustees may invest the funds of the Pharmacopeial Convention, authorize the payment of all moneys due for services performed, transact business involving financial or other matters that may be for the best interests of the Pharmacopeial Convention, and perform such other duties as the Pharmacopeial Convention may direct. Any and all contracts or agreements authorized by the Pharmacopeial Convention or by the Board of Trustees shall be executed on behalf of the Pharmacopeial Convention by the Chairman and the Secretary of the Board of Trustees, or by such other person or persons as the Board may designate.

Section 8. The Board of Trustees shall authorize a general revision of the United States Pharmacopeia, the National Formulary, or other authorized publication at suitable intervals and such supplements during the intervening periods as may be deemed necessary.

Upon receipt of written certification from the Executive Director that a new United States Pharmacopeia or National Formulary or a new supplement has been completed, that each section of it has been approved by the Subcommittee to which its revision or preparation had been assigned, and that it has been approved in its entirety by the Executive Committee of Revision, the Board of Trustees shall then act upon releasing the text and upon designating the date when it is to become official, said date to be reasonably distant from the date of its release. Upon the receipt of written certification from the Executive Director that an authorized publication or supplement has been completed in accordance with the rules and procedures adopted under Section 9, the Board of Trustees shall then act upon releasing the text.

Section 9. The Board of Trustees shall review all rules and procedures made or adopted by the General Committee of Revision and the Executive Committee of Revision and shall determine whether the rules and procedures conflict with the Constitution and Bylaws and whether they are sufficient to insure the accuracy and adequacy of the text of the Pharmacopeia and the National Formulary and other authorized publications. The Board shall determine whether such rules and procedures shall be sufficient to provide adequate notice and opportunity for comment and full and impartial consideration of all proposed changes in, and additions to, the text. Where such conflict or insufficiency is found, the Board shall propose such amendments as may be indicated and, after having given the General Committee of Revision and the Executive Committee of Revision an opportunity to be heard, shall revise or modify the rules and procedures to bring about conformity with the Constitution and Bylaws and to insure their sufficiency.

Section 10. The Board of Trustees shall be informed of the decisions of the Executive Committee of Revision on appeals for reconsideration, revision or abrogation of standards adopted and decisions made by a USP Subcommittee of Revision and, upon consideration of the facts, may request the Executive Committee to review its decision.

Section 11. The advice and consent of the Board of Trustees shall be required for filling vacancies on the General Committee of Revision.

Section 12. Upon recommendation of the Executive Committee of Revision, the Board of Trustees may remove any member of the General Committee of Revision for cause.

Section 13. The Board of Trustees shall issue an annual financial report of the Pharmacopeial Convention audited by a certified public accountant.

Section 14. The Board of Trustees shall arrange for the bonding of Officers and employees to the extent necessary to protect the interests of the Pharmacopeial Convention.

Section 15. The Board of Trustees shall maintain a headquarters for conducting the business of the Pharmacopeial Convention.

Section 16. In the absence of or in the event of the inability of the President and Vice-President to preside at a meeting of the Pharmacopeial Convention, the Board of Trustees shall appoint a President pro tempore to conduct the meeting.

Section 17. During any temporary inability or absence of the Treasurer, an Acting Treasurer may be appointed by the Board of Trustees.

Section 18. At least sixty days prior to each stated meeting of the Pharmacopeial Convention, or at any time in the event of a vacancy in the position, the Board of Trustees shall elect an Executive Director. The Executive Director shall serve at the will of the Board of Trustees. In case of a vacancy in the position of Executive Director, the Chairman of the Board of Trustees shall appoint an Executive Director pro tempore, who shall serve until the Board of Trustees shall have elected an Executive Director. The Board of Trustees may request the advice of the Executive Committee of Revision before electing an Executive Director.

Section 19. The Board of Trustees shall provide for such assistants to the Executive Director as may be deemed necessary.

Section 20. The Board of Trustees shall select four members

of the Pharmacopeial Convention, at least two of whom are representative of the medical and pharmaceutical sciences, who are neither members of the General Committee of Revision or of the Board of Trustees, nor salaried employees or Officers of the Pharmacopeial Convention, to serve on the Nominating Committee for the General Committee of Revision.

Section 21. Prior to each stated meeting of the Pharmacopeial Convention, the Board of Trustees may select not more than twenty persons for their special competence in relation to the administrative or scientific needs of the Pharmacopeia, to be members-at-large of the ensuing Pharmacopeial Convention.

Section 22. Prior to each stated meeting of the Pharmacopeial Convention, the Board of Trustees may select not more than five persons to be members-at-large of the ensuing Pharmacopeial Convention to serve as public members.

Section 23. Prior to each stated meeting of the Pharmacopeial Convention, the Board of Trustees may select not more than five persons to serve as members-at-large of the ensuing Pharmacopeial Convention to represent nations, other than the United States, that give official recognition to the standards of the USP and the NF.

Section 24. The Board of Trustees may designate not more than five organizations as eligible organizations until the next stated meeting and request the appointment of one delegate by each, who, upon approval of the Credentials Committee, shall be seated as a member of the Pharmacopeial Convention.

Section 25. The Board of Trustees may invite the national professional medical and pharmaceutical associations of other nations to send representatives as observers to a stated meeting of the Pharmacopeial Convention.

Section 26. The Chairman of the Board of Trustees shall present a report for the Board at each stated meeting of the Pharmacopeial Convention.

Section 27. The Board of Trustees shall receive from the Secretary abstracts of the stated and special meetings of the Pharmacopeial Convention and shall arrange for their publication.

Section 28. The Board of Trustees shall receive and review any proposition to amend the Constitution and Bylaws and shall recommend such action as it deems advisable as provided in the Constitution and Bylaws.

Section 29. The Board of Trustees shall fill vacancies for unexpired terms of office of the seven elected members of the Board of Trustees, each of whom, at the time of his or her election, shall be a member of the Pharmacopeial Convention; the President, in case the Vice-President is unable to serve; the Vice-President; the Treasurer; and the Executive Director and Secretary; as herein provided.

Section 30. Any officer or member of the Board of Trustees may be removed for cause by the Board of Trustees by an affirmative vote of not less than two-thirds of the members of the Board, other than himself or herself.

Section 31. The Board of Trustees shall approve the outline of specific classifications of service prepared by the Executive Committee of Revision and deemed necessary for the work of the next revisions of the United States Pharmacopeia, the National Formulary, and other authorized publications, and the number of persons to be elected to each classification.

Chapter VII—The General and Executive Committees of Revision

Section 1. The General Committee of Revision shall be composed of appropriately qualified individuals, including public members, together with the Executive Director, ex officio. The General Committee of Revision shall be elected at the stated meeting by a plurality of the votes cast by the members of the Pharmacopeial Convention as provided in these Bylaws. The Executive Director shall be Chairman of the General Committee of Revision.

Section 2. The General Committee of Revision shall be organized by the Executive Director into not fewer than six Subcommittees, each to cover a specific portion of the work of revision. The General Committee of Revision may also be or-

ganized by the Executive Director with the approval of the Board of Trustees into appropriate divisions; each of these may be under the supervision of a Director, who shall act under the authority of the Executive Director. The rosters of the Subcommittees shall be subject to the advice and consent of the General Committee of Revision. The appointment of the Chairmen of the Subcommittees by the Executive Director shall be subject to the approval of the respective Subcommittees.

No person who, during his or her service on the Committee, has a direct or indirect financial interest that conflicts or appears to conflict with his or her duties and responsibilities, may participate in the selection for admission to the United States Pharmacopeia or the National Formulary of therapeutic articles in which he or her has any financial interest.

Section 3. During the period between stated meetings additional Committee members may be added to the Committee of Revision if the Executive Committee and the Board of Trustees determine that such a need exists. Members of the Convention shall be requested to submit the names of persons whose qualifications entitle them to consideration as nominees for membership on the General Committee of Revision. The Executive Committee, insofar as possible, shall nominate twice the number of qualified persons, from among whom the Committee of Revision shall elect the additional Committee members who shall be added to the Committee roster until the next stated meeting.

Section 4. The Chairmen of the Subcommittees and the Executive Director, ex officio, shall constitute the Executive Committee of Revision. The Executive Director shall be Chairman of the Executive Committee.

Section 5. The General Committee of Revision and the Executive Committee of Revision shall make such rules and adopt such procedures, not in conflict with the Constitution and Bylaws, as are sufficient to insure the accuracy and adequacy of the text of the Pharmacopeia and the National Formulary and other authorized publications, and to provide for adequate notice and opportunity for comment and full and impartial consideration of all proposed changes in, and additions to, the text, as may be necessary to the proper discharge of their respective functions. The rules and procedures shall be made available to the Members of the Pharmacopeial Convention for comment. The Committee shall submit the rules and procedures so made or adopted for review by the Board and shall comment upon any proposals made by the latter pursuant to such review.

Section 6. Each Subcommittee shall undertake the revision and preparation of assigned portions of each new Pharmacopeia and National Formulary, and other authorized publications, having regard for the principles of revision laid down by the Pharmacopeial Convention at the last meeting. Upon completion of its assignment, each Subcommittee shall review, with a view to approval, the final text of those portions for which it has been responsible.

Section 7. The General Committee of Revision, through the Executive Director, shall present a report at the stated meeting of the Pharmacopeial Convention.

Section 8. The Chairmen of the Subcommittees shall be members, ex officio, of the Nominating Committee for the General Committee of Revision.

Section 9. A vacancy in the General Committee of Revision shall be filled by the Executive Director with the advice and consent of the General Committee of Revision and of the Board of Trustees.

Section 10. The Executive Committee and the Executive Director shall consult on matters of general policy concerning the planning and executing of the revision of the Pharmacopeia and the National Formulary and other authorized publications and of supplements thereto. The Executive Committee shall review, with a view to approval, the proposals of all Subcommittees and other committees for monographs on articles newly admitted and for revisions of, additions to, and deletions from existing text. The Executive Committee shall authorize that appropriate publicity be given to all such proposals prior to their final approval and shall consider suggestions for changes arising from the publicity thus given.

Section 11. The Executive Committee of Revision shall receive and rule upon all appeals for reconsideration, revision or abrogation of standards adopted and decisions made by a USP Subcommittee. Each decision of the Executive Committee of Revision on such appeals shall be referred to the Board of Trustees which, upon consideration of the facts, may request the Executive Committee to review its decision. After such review, which shall be given as promptly as practicable, the Executive Committee may reaffirm its decision by an affirmative vote of four-fifths of the members of the Committee. Lacking a four-fifths affirmative vote, the question shall be returned to the USP Subcommittee concerned for additional study.

Section 12. The Executive Committee of Revision shall approve the completed text before a new United States Pharmacopeia or a new National Formulary or a new supplement is released for publication.

Section 13. At least one year before the stated meeting of the Pharmacopeial Convention, the Executive Committee of Revision shall prepare and publish an outline of specific classifications of service deemed necessary to the efficient prosecution of the work of the next revisions of The United States Pharmacopeia and the National Formulary and other authorized publications and a statement of the number of persons to be elected in each classification. Upon approval of the Board of Trustees, this outline shall be followed in submitting to the Nominating Committee for the General Committee of Revision the names of persons to be considered for membership on the General Committee of Revision that is to be elected at the forthcoming stated meeting of the Pharmacopeial Convention.

Section 14. The Executive Committee of Revision may recommend to the Board of Trustees the removal, for cause, of any member of the General Committee of Revision.

Chapter VIII—The Committee on Resolutions

Section 1. The Committee on Resolutions, hereinafter referred to in this Chapter as the Committee, shall consist of five members of the Pharmacopeial Convention.

Prior to the stated meeting of the Pharmacopeial Convention, the President shall appoint five members of the Pharmacopeial Convention to serve as members of the Committee, one of whom shall be designated as Chairman, and such additional associates, who need not be members of the Convention, as may be required to aid the Committee.

Section 2. The Committee shall be responsible for reviewing the recommendations made in the addresses and reports of the Officers, Committees, and Board of Trustees; reviewing resolutions that have been submitted to it in written form at least 30 days prior to a stated meeting by eligible organizations and prior to the first session by individual members of the Pharmacopeial Convention, conferring with the parties concerned whenever necessary about the intent or any other aspect of the resolution; for drafting statements in resolution form that shall reflect the official policy of the Pharmacopeial Convention; and for presenting all resolutions to the Convention for consideration, unless later introduction of a resolution by a member is permitted by two-thirds vote of the members present and voting.

Section 3. The Committee shall make an initial report in at least one session prior to the Final Session of the meeting; the final report of the Committee and the vote on the resolutions submitted by the Committee shall be conducted in the Final Session.

Chapter IX—The Nominating Committee for Officers and Trustees

Section 1. The Nominating Committee for Officers and Trustees, hereinafter referred to in this Chapter as the Committee, shall consist of five members of the Pharmacopeial Convention, one of whom shall be designated as Chairman, appointed by the President with the advice and consent of the Board of Trustees, not later than six months before the stated meeting.

Section 2. The Committee shall nominate from the membership of the Pharmacopeial Convention or the General Committee of Revision two members for the office of President,

two members for the office of Vice-President, and one or more persons, who need not be members of the Convention, for the office of Treasurer.

Section 3. The Committee shall nominate from the membership of the Pharmacopeial Convention or the General Committee of Revision fourteen members for the elected office of Trustee, divided into four classes: four shall represent pharmaceutical sciences; four shall represent medical sciences; four shall be without restriction concerning their affiliations; and two shall represent the public.

Section 4. The report of the Committee shall be submitted to the Secretary of the Pharmacopeial Convention not later than sixty days before the stated meeting; not later than forty-five days before the stated meeting, the Secretary shall notify the nominees of their selection by the Committee and the date of the stated meeting.

Section 5. The Committee shall present its report to the Convention, at which time additional nominations of Convention or Committee of Revision members may be made from the floor for Officers and the Board of Trustees, which shall be seconded by at least four members of the Pharmacopeial Convention and submitted in writing at once to the Secretary. A nomination for Trustee shall indicate in which of the four classes the nomination is being made.

Chapter X—The Nominating Committee for the General Committee of Revision

Section 1. The Nominating Committee for the General Committee of Revision, hereinafter referred to in this Chapter as the Committee, shall consist of the Chairmen of the Subcommittees of the General Committee of Revision, ex officio, together with four members of the Pharmacopeial Convention at least two of whom are representative of the medical and pharmaceutical sciences, selected by the Board of Trustees, as provided in Chapter VI, Section 20, of these Bylaws. The President of the Pharmacopeial Convention and the Executive Director shall be members, ex officio, of the Committee.

The Committee shall be organized at least one year prior to the stated meeting of the Pharmacopeial Convention and shall elect its own Chairman. The Secretary of the Convention shall serve as Secretary of the Committee.

Section 2. Not later than seven months prior to the stated meeting of the Pharmacopeial Convention, the Secretary of the Committee shall issue to all who are entitled to representation in the Pharmacopeial Convention, as provided in Article II, Section 1, of the Constitution, and to the members of the General Committee of Revision, a request that they submit the names of persons whose qualifications entitle them to consideration as nominees for membership on the General Committee of Revision. Each name submitted shall be accompanied by a statement on an official form supplied by the Committee indicating affiliations, academic and professional backgrounds, and the qualifications for the specific classification or classifications of membership on the General Committee of Revision as set forth in the outline referred to in Chapter VII, Section 13, of these Bylaws. All recommendations shall be mailed to the Secretary of the Pharmacopeial Convention not later than one hundred and twenty days prior to the stated meeting.

All recommendations received by the Secretary shall be submitted to the Committee not later than ninety days prior to the stated meeting and shall be given primary consideration by the Committee in selecting nominees for membership on the General Committee of Revision.

Section 3. At the stated meeting of the Pharmacopeial Convention, the Committee shall submit, through the Secretary, to each member, a list of names of persons whom it deems qualified to serve on the General Committee of Revision, together with a statement covering the classification or classifications of the work of revision for which each nominee is deemed best qualified, and the affiliations, academic and professional backgrounds and specific qualifications of each nominee.

The Committee shall nominate, insofar as possible, twice the number of qualified persons to be elected to meet each need

shown in the outline referred to in Chapter VII, Section 13, of these Bylaws.

Additional nominations may be made from the floor for membership on the General Committee of Revision and shall be seconded on the floor by at least four members of the Pharmacopeial Convention. Each such nomination shall be submitted on the official form and presented at once to the Secretary of the Pharmacopeial Convention.

Chapter XI—The Credentials Committee

Section 1. The Credentials Committee shall consist of five members and shall be appointed by the President, who shall also appoint the Chairman, not later than sixty days after the stated meeting of the Pharmacopeial Convention. The Chairman of the Board of Trustees, and the President, and the Secretary of the Pharmacopeial Convention shall be members, ex officio, of the Credentials Committee. Members of the Credentials Committee shall retain their Pharmacopeial Convention membership until their successors are appointed.

Section 2. The Credentials Committee shall examine carefully the credentials of all delegates or alternate delegates in the absence of delegates. Credentials issued in blank, with the names of the delegates and alternate delegates to be inserted subsequently by other than the regularly constituted officers of the appointing educational institution, organization, or designated division of the Federal Government shall not be accepted. Credential forms presented for the first time at a meeting shall be independently verified before acceptance. Immediately prior to the opening of the stated meeting of the Pharmacopeial Convention, the Committee shall furnish to the Secretary of the Pharmacopeial Convention a list of delegates whose credentials have been approved by the Committee and a list of alternate delegates whom it has approved in lieu of delegates who are absent.

Section 3. The Credentials Committee shall make a report to the Pharmacopeial Convention concerning all credentials that have not been approved. A majority vote of the members of the Pharmacopeial Convention shall be required to overrule a decision of the Credentials Committee.

Chapter XII—Members

Section 1. Each delegate shall present his credentials to the Credentials Committee and, upon report by that Committee that the credentials are approved, shall be accredited and be seated as a member. If a delegate is absent from the stated meeting the alternate delegate shall present credentials as Alternate Delegate to the Credentials Committee and, upon report that the credentials are approved, shall be accredited and be seated as the member for that stated meeting.

Section 2. The Officers of the Pharmacopeial Convention, the Board of Trustees, the Chairmen of Committees directed to report at the stated meeting, serving by authority of the preceding stated Pharmacopeial Convention or the Constitution and Bylaws shall be members, ex officio, of the Pharmacopeial Convention. The persons selected by the Board of Trustees as members-at-large shall be members of the Convention.

Section 3. Nominees selected by the Nominating Committee for Officers and Trustees for the Board of Trustees, the office of President and the office of Vice-President 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 (d), of the Bylaws, whether present or not.

Section 4. A member of the Pharmacopeial Convention shall continue to be a member until the next stated meeting of the Convention unless he or she dies, resigns, or fails to meet the requirements as provided in Article II, Section 3, of the Constitution or until his or her successor has been authorized by the Eligible Organization and his or her successor's credentials approved by the Credentials Committee.

Section 5. A member shall represent not more than one educational institution, organization, or designated division of the Federal Government.

Section 6. A member may be expelled for improper conduct

or for violation of the Constitution and Bylaws, by a vote of not less than two-thirds of the members present and voting.

Section 7. Resignations of membership in the Pharmacopeial Convention shall be submitted in writing to the Secretary of the Convention. All resignations shall be acknowledged in writing by the Secretary and shall be reported to the Board of Trustees.

Chapter XIII—Meetings

Section 1. Meetings of the Pharmacopeial Convention shall be held as provided in Article VI of the Constitution.

The call for a stated meeting of the Pharmacopeial Convention shall be issued as provided in Chapter I, Section 6, of these Bylaws.

The call for a special meeting of the Pharmacopeial Convention shall state the purpose for which the meeting is called, and shall be mailed by the Secretary to all members and to all those entitled to representation under the Constitution, not later than sixty days prior to the meeting. The business of a special meeting shall be limited to the purpose for which the meeting has been called.

Section 2. Each stated or special meeting of the Pharmacopeial Convention shall consist of an opening and a final session, and such number of intervening sessions as the Convention may direct in order to conduct the business of the Convention. At least one hour shall elapse between any two sessions, and no session shall be opened at a time earlier than that announced at the session immediately preceding.

Any session may be recessed by a majority vote and shall be reconvened at the time specified in the recess motion.

Section 3. The Secretary, with the advice of the President, shall prepare the order of business for each stated meeting and shall distribute it to the Members, Delegates, and Alternate Delegates at least 30 days prior to the meeting. That order of business shall govern unless otherwise directed by the affirmative votes of not less than two-thirds of the members present and voting.

On all questions of procedure, the latest edition of Robert's

Rules of Order, Newly Revised, shall prevail, unless otherwise specified herein.

Chapter XIV—The Corporate Seal

The seal of the Corporation shall contain the words: "The United States Pharmacopeial Convention. Corporate—1900—seal, D. C."

Chapter XV—Amendments

Section 1. Every proposition to amend these Bylaws, except as hereinafter provided, shall be submitted in accordance with the procedures to amend the Constitution as set forth in Article VIII, Sections 1 and 2, of the Constitution, and shall, under either procedure, upon receiving the affirmative votes of not less than three-fourths of the members present and voting, become a part of these Bylaws.

Section 2. The Board of Trustees may at its discretion mail to the members of the Pharmacopeial Convention a proposition to amend or alter these Bylaws. A period of sixty days shall be allowed for the submission of comments on the proposition. A summary of the comments shall accompany the mail ballot by which the vote of the member may be recorded and returned within ninety days of the date printed on the ballot. Upon receiving the affirmative vote of seven-eighths of the members voting, with a total of not less than one hundred members voting, it shall become a part of these Bylaws.

Chapter XVI—Dissolution

In the event of dissolution of the Corporation, the Board of Trustees shall after paying or making provision for the payment of all of the liabilities of the Corporation, dispose of all of the assets exclusively for the purposes of the Corporation in such manner as the Board of Trustees shall determine to such organization or organizations, organized and operated exclusively for charitable, educational or scientific purposes as at the time shall qualify as an exempt organization or organizations under Section 501(c) (3) of the Internal Revenue Code of 1954 (or the corresponding provision of any future United States Internal Revenue Law).

Admissions

New Monographs Appearing for the First Time in This Supplement

USP XX

Amoxicillin Tablets
Ascorbic Acid Oral Solution
Azatadine Maleate
Bacampicillin Hydrochloride
Bacitracin Zinc Ointment
Sterile Bacitracin Zinc
Bromocriptine Mesylate
Bromocriptine Mesylate Tablets
Carbidopa and Levodopa Tablets
Castor Oil Emulsion
Cefadroxil Tablets
Sterile Cefotaxime Sodium
Cinoxacin
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NF XV

Diethyl Phthalate

Changes in Official Titles, Appearing for the First Time in This Supplement

New Title

Methenamine and Monobasic Sodium Phosphate Tablets
Monobasic Sodium Phosphate

Former Title

Methenamine and Sodium Biphosphate Tablets
Sodium Biphosphate

Important—New Changes Adopted Since the Previous Supplement and Addendum and the Second and Third Interim Revision Announcements Were Published Pertain to the Following Titles.

ANNOTATED LIST

Monographs, General Chapters, Reagents, and Tables Affected by Changes Appearing for the First Time in This Supplement

Page citations refer to the pages of this Supplement.

Note—The absence of a parenthetical term after the section heading denotes a change in the text, as distinguished from a newly added or deleted section.

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