Mission and Preface

USP 38–NF 33 and Supplements

This section provides background information on the United States Pharmacopeial Convention (USP), as well as general information about the 38th revision of the United States Pharmacopeia (USP 38) and the 33rd edition of the National Formulary (NF 33) and their Supplements. Unless otherwise noted, the text in USP 38–NF 33 is official May 1, 2015, the text in the First Supplement to USP 38–NF 33 is official August 1, 2015, and the text in the Second Supplement to USP 38–NF 33 is official December 1, 2015.

MISSION STATEMENT

USP–NF is published in continuing pursuit of the mission of USP: To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.

HISTORY

On January 1, 1820, 11 physicians met in the Senate Chamber of the U.S. Capitol building to establish a pharmacopeia for the United States. These practitioners sought to create a compendium of the best and most fully established medicines, give them useful names, and provide recipes for their preparation. Nearly one year later, on December 15, 1820, the first edition of The Pharmacopoeia of the United States was published. After time, the nature of the United States Pharmacopeia (USP) changed from being a compendium of recipes to a compendium of documentary standards for identity and quality that typically involve reference materials used as comparison standards in specified tests and assays. The publishing schedule of USP also changed over time. From 1820 to 1942, USP was published at 10-year intervals; from 1942 to 2000, at five-year intervals; and beginning in 2002, annually.

In 1888 the American Pharmaceutical Association published the first National Formulary under the title The National Formulary of Unofficial Products (NF). Both USP and NF were recognized in the Federal Food and Drugs Act of 1906 and again in the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act). In 1975, USP acquired the National Formulary (NF), which now contains excipient standards that also call for reference materials. USP continues to develop USP and NF, through the work of the Council of Experts, into compendia that provide standards for articles based on advances in analytical and metrological science. As these and allied sciences evolve, so do USP and NF.

CONTENT OF USP–NF

USP–NF contains official substance (ingredient) and product monographs for official articles recognized in USP–NF. The terms official substance, official preparation, and official article are defined in the General Notices and Requirements (General Notices). With few exceptions, all articles for which monographs are provided in USP–NF are legally marketed in the United States or are contained in legally marketed articles. USP–NF also includes monographs for compounded preparations.

A USP–NF monograph for an official substance, product, or preparation may consist of various components, including the article’s name; definition; packaging, storage, and other requirements; and a specification. The specification consists of a series of universal tests (description, identity/identification, impurities, assay) and specific tests, one or more analytical procedures for each test, and acceptance criteria. Ingredients are defined as either drug substances or excipients. An excipient is any component, other than the active substance(s), intentionally added to the formulation. Excipients are not necessarily inert. Drug substances and excipients may be synthetic, semi-synthetic, drawn from nature (natural source), or manufactured using recombinant technology. Drugs that consist of larger molecules and mixtures requiring a potency test are usually referred to as biologicals or biotechnological articles.

General chapters provide frequently cited procedures, sometimes with acceptance criteria, in order to compile into one location repetitive information that is applicable to many monographs. New and revised monographs and general chapters and omitted monographs from this edition are indicated in the Admissions section.

USP–NF Organization—USP–NF is printed as a four-volume set. Volume 1 includes front matter (Mission and Preface, People, governance pages and websites, and Admissions/Annotations). It also includes USP General Notices, General Chapters, Dietary Supplements general chapters, Reagents, and Reference Tables. Volume 2 includes USP monographs A–I, and Volume 3 includes USP monographs J–Z. Volume 4 includes Dietary Supplements monographs, NF Admissions/Annotations, Excipients, and NF monographs. To facilitate convenient use and reference, all four volumes include the combined index, as well as the USP General Notices and the Guide to General Chapters. General chapters specific to dietary supplements are included in numerical order with the rest of the general chapters in USP. Excipient monographs are usually presented in NF but also may appear in USP with suitable cross-referencing when they are also drug substances. The Excipients section (Volume 4) presents a tabulation of excipients by functional category.

Revisions to USP–NF—USP–NF is continuously revised. Revisions are presented annually as Standard Revisions in USP–NF and in twice-yearly Supplements, and as Accelerated Revisions on USP’s website (Errata, Interim Revision Announcements, and Revision Bulletins). Standard Revisions—USP’s Standard Revisions process calls for publication of a proposed revision in the Pharmacopeial Forum (PF) for a 90-day notice and comment period and, after the revision is approved by the relevant USP Expert Committee, publication in the next USP–NF or Supplement, as applicable. Accelerated Revisions—The Accelerated Revision process is used to make revisions to USP–NF official more quickly than through USP’s Standard Revision process. Accelerated Revisions, which include Errata, IRAs, and Revision Bulletins, are...
posted on USP’s website, do not always require notice and comment, and allow for a revision to become official before the next USP±NF or Supplement. See the USP Guideline on Use of Accelerated Processes for Revisions to the USP±NF, which is posted on USP’s website. Errata—An Errata is content erroneously published in a USP publication that does not accurately reflect the intended official or effective requirements as approved by the Council of Experts. These typically are changes that do not have a broad impact on the standards. Errata are not subject to public comment and are communicated to the stakeholders by posting in the “Official Text” section of USP’s website. Errata are no longer published in the USP±NF and Supplement print products, but rather are posted on USP’s website. Errata become official on the first day of the month following their posting to the USP website. Errata are incorporated into the next available USP±NF or Supplement and are tagged when printed as described below.

Interim Revision Announcements (IRAs)—An IRA appears in PF first as a Proposed Interim Revision Announcement with a 90-day comment period. If there are no significant comments, the IRA becomes official in the “Official Text” section of USP’s website, with the official date indicated. IRAs are incorporated into the next available USP±NF or Supplement.

Revision Bulletins—If circumstances require rapid publication of official text, a revision or postponement may be published through a Revision Bulletin. Revision Bulletins are posted on USP’s website with the official date indicated. Revision Bulletins are incorporated into the next available USP±NF or Supplement.

Modification of Compendial References—USP and its Expert Committees periodically deem it necessary to modify general chapter titles or similar text that may be referenced in other standards throughout the USP±NF. When this occurs, USP staff undertake a rigorous process for identifying and updating such references. These updates may occur through a routine revision, or, in cases in which an update appears to present no significant change in the affected standard, through a direct update of the reference in that standard without providing an opportunity for notice and comment. In all cases, USP will publish on its website a notice indicating the scope of change, any resulting references, and whether those references will be updated through a routine revision or a direct update.

Updating Chemical Information—Updates to the Chemical Information section at the beginning of monographs occur on an ongoing basis and are not identified with revision symbols. Chemical names and molecular weights are updated when a monograph undergoes revision to match the official source, United States Adopted Names (USAN). Chemical structures are updated on a continuous basis.

Chemical names typically reflect the naming conventions at the time of the monograph development or revision. If the nomenclature rules of CAS or IUPAC are significantly changed, the chemical names can be revised or added to implement those rules. Molecular weights are derived from the chemical formula and are based on the table of atomic weights. Atomic weights are recommended by the IUPAC and reflect the isotopic composition of normal terrestrial material. When the IUPAC recommended values are changed, it is understood that the changes in molecular weights will be made in due course.

Graphical representation of the chemical compound structures is intended to help establish chemical identity and is understood to represent one of many possible ways to depict the molecule. Changes in the graphical representation resulting in the same chemical information, e.g., a flipped chiral molecule, may be introduced outside of the revision process. It is also understood that in the case of tautomerism, the molecule depicted may be one of the tautomers, but it is understood that it is intended to represent all isomers in equilibrium. Stereogenic centers depicted with plain bonds imply mixtures of pertinent stereomers—enantiomer, diastereomers, epimers (anomers), etc.

Depending on the timing of these updates, users may see a difference in a chemical structure between the publications in PF and USP±NF, and between the USP±NF print version and the online version.

Pharmacopeial Forum (PF)—The PF is USP’s public notice and comment vehicle. Proposals for revision are presented in the In-Process Revision or the Proposed Interim Revision Announcement (see above) sections and represent draft revisions that are expected to advance to official status pending final review and approval by the relevant Expert Committee. PF is available online only and is free of charge. This is intended to help facilitate open and public participation in the USP±NF revision process. PF includes proposed changes and additions to the USP±NF, including Stage 4 Harmonization, and Stimuli articles for which USP is seeking public comments. All proposals, including IRAs, have a 90-day comment period.

Supplements—Supplements to USP±NF follow a standard schedule each year: the First Supplement is published in February and becomes official August 1. The Second Supplement is published in June and becomes official December 1. Users of USP print products must retain Supplements and check the “Official Text” section of USP’s website to have up-to-date official text. The USP±NF online version is updated with each Supplement or annual revision. Each time a new edition or Supplement is released during the subscription period, a new electronic version is issued. The Index in each Supplement is cumulative and includes citations to the annual revision and, for the Second Supplement, citations to the First Supplement. The contents of the two Supplements are integrated into the annual edition of the following year, along with new official revisions that have been adopted since the Second Supplement to the previous compendia.

USP±NF Translations—Translations of the USP±NF are available in Spanish, Russian, and Chinese. The Spanish translation is current; other translations are based on previous revisions of the USP±NF.

USP Reference Standards—The use of USP Reference Standards promotes uniform quality of drugs and supports reliability and consistency by those performing compliance testing and other users of USP±NF, including manufacturers, labelers, and regulatory authorities. USP Reference Standards are referenced in specific procedures in both monographs and general chapters. USP advances this material via careful characterization studies and collaborative testing, followed by review and approval of the compendial use of the reference material by Expert Committees of the Council of Experts. The USP Catalog, which lists the collection of USP Reference Standards, can be accessed on USP’s website (www.usp.org). This program benefits from the widespread voluntary contribution of suitable materials and test data from pharmaceutical manufacturers.

Shading and Symbols—Shading is used to identify text that has been modified, added, or deleted since it was last published. Symbols identify the beginning and end of each revision or nonharmonized text. The following table summarizes the types of symbols and the associated subscripts used in USP publications:

<table>
<thead>
<tr>
<th>Revision Type</th>
<th>Symbol</th>
<th>Subscript</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Revision</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Announcement</td>
<td>(IRA 1-Jul-2014)*</td>
<td></td>
</tr>
<tr>
<td>Revision Bulletin</td>
<td>(RB 1-Jan-2014)*</td>
<td></td>
</tr>
<tr>
<td>Text deletion</td>
<td>(IRA 1-Jul-2014) or (IRA 1-Jul-2014)*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(USP38)*</td>
<td></td>
</tr>
</tbody>
</table>

* A subscript number or date indicates the IRA, Revision Bulletin, or Supplement in which the revision first appeared.
** An example of a revision that was officially adopted in the USP±NF would be (USP38).
Revision Type | Symbol | Subscript
---|---|---
Adopted in Supplement | • new text | USP annual edition
Adopted in USP-NF | • new text | USP annual edition
Harmonization | • residual national text or nonharmonized text | *A subscript number or date indicates the IRA, Revision Bulletin, or Supplement in which the revision first appeared.

**An example of a revision that was officially adopted in the USP-NF would be above.**

The following table shows symbols and official dates for IRAs and Supplements to USP 38–NF 33:

<table>
<thead>
<tr>
<th>IRA</th>
<th>Proposed Supplement</th>
<th>Official Date</th>
<th>Symbols</th>
</tr>
</thead>
<tbody>
<tr>
<td>41(1)</td>
<td>July 1, 2015</td>
<td>• and •</td>
<td>(IRA 1-Jul-2015)</td>
</tr>
<tr>
<td>1</td>
<td>Aug. 1, 2015</td>
<td>• and •</td>
<td>(IRA 1-Aug-2015)</td>
</tr>
<tr>
<td>41(2)</td>
<td>Sept. 1, 2015</td>
<td>• and •</td>
<td>(IRA 1-Sep-2015)</td>
</tr>
<tr>
<td>41(3)</td>
<td>Nov. 1, 2015</td>
<td>• and •</td>
<td>(IRA 1-Nov-2015)</td>
</tr>
<tr>
<td>2</td>
<td>Dec. 1, 2015</td>
<td>• and •</td>
<td>(IRA 1-Dec-2015)</td>
</tr>
<tr>
<td>41(4)</td>
<td>Jan. 1, 2016</td>
<td>• and •</td>
<td>(IRA 1-Jan-2016)</td>
</tr>
<tr>
<td>41(5)</td>
<td>Mar. 1, 2016</td>
<td>• and •</td>
<td>(IRA 1-Mar-2016)</td>
</tr>
<tr>
<td>41(6)</td>
<td>May 1, 2016</td>
<td>• and •</td>
<td>(IRA 1-May-2016)</td>
</tr>
</tbody>
</table>

Harmonization) that has not yet been published in the USP–NF or its Supplements.

**USP GOVERNING, STANDARDS-SETTING, AND ADVISORY BODIES**

USP’s governing, standards-setting, and advisory bodies include the USP Convention, the Board of Trustees, the Council of Experts and its Expert Committees, Expert Panels, and staff. Additional volunteer bodies include Stakeholder Forums, Project Teams, and Advisory Groups, which act in an advisory capacity to provide input to USP’s governing, standards-setting, and management bodies.

**USP Convention**—The composition of the USP Convention membership is designed to ensure a global representation from all sectors of health care, with an emphasis on practitioners, given USP’s practitioner heritage (see the History section). Voting Delegates of Convention member organizations elect USP’s President, Treasurer, other members of the Board of Trustees, and the Council of Experts. They also adopt resolutions to guide USP’s strategic direction and amend USP’s Bylaws. Convening on a five-year cycle, the most recent meeting of the USP Convention occurred in April 2015 in Washington, D.C. A listing of all current Voting Delegates of the USP Convention is included in the People section.

**Board of Trustees**—USP’s Board of Trustees is responsible for the management of the business affairs, finances, and property of USP. During its five-year term, the Board defines USP’s strategic direction through its strategic plan and its key policy and operational decisions. A listing of the members of the 2010–2015 Board of Trustees is included in the People section.

**Council of Experts and Expert Committees**—The Council of Experts is the standards-setting body of USP. As of this publication, it is composed of 26 members, each of whom chairs an Expert Committee. Members of the Council of Experts were either elected to five-year terms by USP’s Convention or, for Chairs of Expert Committees created during the cycle, elected by the existing Council of Experts for the remainder of the cycle. These Chairs in turn elect the members of their Expert Committees. The Expert Committees are responsible for the content of USP’s official and authorized publications (see Figure 1). The Executive Committee of the Council of Experts includes all Expert Committee Chairs and provides overall direction, is an appeals body, and performs other functions that support the Council of Experts’ operations.

**Expert Panels**—The Chair of the Council of Experts may appoint Expert Panels to assist the Council of Experts by providing advisory recommendations to particular Expert Committees in response to a specific charge consistent with the Expert Committee’s Work Plan. Expert Panels are continuously formed; their topics and membership appear in the People section.

**Stakeholder Forums and Project Teams**—USP has formed several domestic and international Stakeholder Forums and Project Teams to exchange information on the use and implementation of USP’s standards. Stakeholder Forums may form Project Teams to work on selected topics. The current USP Stakeholder Forums follow.

**North American Stakeholder Forums** (United States and Canada)
- Prescription/Nonprescription
- Dietary Supplements
- Excipients
- Food Ingredients
- Veterinary Drugs

**International Stakeholder Forums**
- India
- Mexico
- Brazil

Also, in the online version of the USP–NF, monographs and general chapters that have been revised but not yet published in the USP–NF or its Supplements (e.g., as Accelerated Revisions) will contain icons that will link to the page on the USP website where the new official text can be viewed. These icons will link to Accelerated Revisions (Revision Bulletins, Interim Revision Announcements, and Errata) and Stage 6 Harmonization (see Harmonization below).

**Commentary**—For revisions that are published for public review and comment in PF, the proposal may advance to official status or be republished in PF for further notice and comment. If comments are received, they are considered and incorporated as appropriate by the Expert Committee(s). In cases where proposals advance to official status without republication in PF, a summary of comments received and the appropriate Expert Committee’s responses are published in the Commentary section of the USP website at the time the revision is published.

The Commentary is not part of the official text and is not intended to be enforceable by regulatory authorities. Rather, it explains the basis of the Expert Committee’s response to public comments. If there is a difference between the contents of the Commentary and the official text, the official text prevails. In case of a dispute or question of interpretation, the language of the official text, alone and independent of the Commentary, shall prevail.

**Print and Electronic Presentations**—USP–NF and its two annual Supplements are available in print form, on a USB drive, and in an online format. The online format allows individual registered users to access the USP–NF through the Internet. The USB drive version makes USP–NF accessible to users on their computers without requiring an Internet connection. Both electronic formats are cumulatively updated to integrate the content of Supplements. Monographs and general chapters in the online USP–NF are updated with icons that link to USP’s website for official text (Revision Bulletins, IRAs, Errata, and Stage 6 Harmonization)
Mission and Preface

USP 38

Authority for Publication—USP–NF is published in accordance with Article II, Purposes, of the USP Bylaws, which states, “The purposes for which the Convention is formed are as set forth in the Articles of Incorporation and include developing and disseminating public standards for medicines and other articles, and engaging in related public health programs.”

USP–NF REVISION PROCESS

Public Participation—Although USP’s Council of Experts is the ultimate decision-making body for USP–NF standards, these standards are developed by an exceptional process of public involvement and substantial interaction between USP and its stakeholders, both domestically and internationally. Participation in the revision process results from the support of many individuals and groups and also from scientific, technical, and trade organizations.

Updates to the USP–NF—USP has several mechanisms by which it updates the USP–NF with new monographs or revisions to existing monographs. One mechanism is the donor model by which monograph or general chapter information is voluntarily submitted to USP by manufacturers or other interested parties. In this case, the donor submits the
information through a Request for Revision. USP has prepared a document titled Monograph Submission Guideline to facilitate monograph submission (available at www.usp.org; search on “Monograph Submission Guideline”). Another way in which USP updates its standards is through USP laboratory-developed procedures. USP laboratories can develop individual identification, assay, and impurity procedures for inclusion in a proposed standard. USP also collaborates with other pharmacopias to incorporate already developed standards into the USP±NF. All standards, regardless of source, are proposed in PF for public review and comment. Figure 2 shows the public review and comment process and its relationship to standards development.

Working with the Food and Drug Administration—As specified by U.S. law, USP works with the Secretary of the Department of Health and Human Services, and the principal agency in the Department for this work is the Food and Drug Administration (FDA). USP works in many ways with the agency, but the primary interaction is through the FDA Liaison Program. The Liaison Program allows FDA representatives to participate in Expert Committee and Expert Panel meetings, enabling interactions between FDA scientific staff and Expert Committees. Staff in the FDA Centers who are responsible for review of compendial activities provide specific links and opportunities for exchange of comments. Dr. Paul Seo in the Center for Drug Evaluation and Research provides a primary compendial point of contact between FDA and USP. Other ways in which USP works with FDA include collaborating on specific topics, such as monograph modernization, and working internationally.

LEGAL RECOGNITION

Recognition of USP±NF—USP±NF is recognized by law and custom in many countries throughout the world. In the United States, the FD&C Act defines the term “official compendium” as the official USP, the official NF, the official Homeopathic Pharmacopeia of the United States, or any supplement to them. As noted below (and in General Notices section 2.30), USP±NF standards play a role in the adulteration and misbranding provisions of the FD&C Act (which apply as well to biologics, a subset of drugs, under the Public Health Service Act). USP has no role in enforcement of these or other provisions that recognize USP±NF standards, which is the responsibility of FDA and other government authorities in the United States and elsewhere.

Under the relevant FD&C Act provisions, a drug will be deemed misbranded unless its label bears to the exclusion of any other nonproprietary name the “established” name, which ordinarily is the compendial name (see discussion Nomenclature, below). A drug with a name recognized in USP±NF must comply with the identity/identification requirements of its monograph, or be deemed adulterated, misbranded, or both. Drugs also must comply with compendial standards for strength, quality, and purity (assays and tests for impurities), unless labeled to show all respects in which the drugs differ. FDA requires that names for articles that are not official must be clearly distinguished and differentiated from any name recognized in an official compendium. Drugs with a name recognized in USP±NF also will be considered misbranded unless they meet compendial standards for packaging and labeling.

Drugs—USP’s goal is to have substance and drug product monographs in USP±NF for all legally marketed drugs in the United States, including chemical and biologic medicines, and their ingredients. USP also develops monographs for legally marketed therapeutic products not approved by FDA, e.g., pre-1938 drugs, over-the-counter (OTC) drugs marketed under FDA’s OTC Monograph system, dietary supplements, and compounded preparations. Conformance with a USP±NF monograph, if applicable, is required at all times in the life of an article from production to expiration.

Biologics—In the United States, biologics are considered to be a subset of drugs, whether they are approved by FDA under the FD&C Act and receive a new drug application (NDA) or under the Public Health Service Act (PHS Act,
where they receive a biologics license application (BLA). As a result, all PHS Act biologics are subject to the drug regulatory requirements of the FD&C Act, which means they are required to comply with the adulteration and misbranding provisions of the FD&C Act with all USP-NF compendial requirements. This is equally so for biologics approved under the longstanding PHS Act “351(a)” pathway, as well as the new “351(k)” pathway for biosimilars added by the 2010 healthcare reform legislation (Biologics Price Competition and Innovation Act, Title VII, Subtitle A of the Patient Protection and Affordable Care Act, Public Law 111-148).

Medical Devices—Section 201(h) of the FD&C Act designates a device as an instrument, apparatus, similar article, or component thereof recognized in USP-NF. Section 502(e) of the FD&C Act defines the established name of a device in the absence of an FDA designation of the official name as the official title in an official compendium. Despite these statutory provisions, there is no comparable recognition of USP’s role in establishing compendial standards for medical devices as exists for drugs and biologics. Under authority granted by the Food and Drug Administration Modernization Act of 1997, the Center for Devices and Radiological Health recognizes national and international standards, including some USP tests and assays, for medical devices.

Dietary Supplements—The Dietary Supplement Health and Education Act of 1994 amended the FD&C Act to provide that a dietary supplement may be deemed a misbranded food if it is covered by the specifications of an official compendium (e.g., USP-NF). Section 502(e) of the FD&C Act defines the establishment of the official name of a device in the absence of an FDA designation of the official name as the official title in an official compendium. However, the FDA is not required to comply with the adulteration and misbranding provisions of the FD&C Act, which means they are subject to the FD&C Act regulations. The USP Dictionary of USAN and International Drug Names (see USP Dictionary, below).

Chemical Names and CAS Registry Numbers—Chemical subtitles given in the monographs are index names used by the Chemical Abstracts Service (CAS) of the American Chemical Society. They are provided only in monographs in which the titles specify substances that are definable chemical entities. The first subtitle is the inverted form of the systematic chemical name developed by CAS for the purpose of the Collective Index (CI). The second subtitle, given in uninveted form, is a preferred IUPAC name (PIN) sanctioned and used by the International Union of Pure and Applied Chemistry (IUPAC). Preferred IUPAC names also are used by the World Health Organization (WHO). Occasionally a third subtitle is supplied for historical reasons or when the synonym uses an alternative, but equivalent, naming convention. Monographs with chemical subtitles also generally carry CAS registry numbers. These bracketed numbers function independently of nomenclature as invariant numerical designators of unique, unambiguous chemical substances in the CAS registry, and thus are convenient and widely used.

HARMONIZATION ACTIVITIES

Pharmacopeial Discussion Group—USP harmonizes pharmacopeial excipient monographs and general chapters through the Pharmacopeial Discussion Group (PDG), which includes representatives from the European, Japanese, and United States pharmacopoeias, and WHO (as an observer). According to the PDG definition, “a pharmacopeial general chapter or other pharmacopeial document is harmonized when a pharmaceutical substance or product tested by the document’s harmonized procedure yields the same results, and the same accept/reject decision is reached.” Information regarding PDG, including history, the PDG working procedure, a glossary, and lists of monographs and general chapters that have completed stages 1–6 of the pharmacopeial harmonization process resulting in an approved USP Stage 6 Harmonization text, is available on USP’s website.

Other Harmonizing Activities—USP is participating in several harmonizing activities that include all pharmacopoeias. These activities, while currently in progress, are working toward Good Pharmacopoeial Practices and optimal public standards for all medicines.

OTHER USP COMPENDIA

USP Medicines Compendium—The USP Medicines Compendium (MC) is an online compendium that includes monographs, general chapters, and reference materials for suitable chemical and biological medicines and their ingredients approved by national regulatory authorities in any country. The purpose of the MC is to help ensure that these medicines are of good quality by providing up-to-date, relevant public standards and reference materials. MC standards
are available to manufacturers, purchasers, national regulatory authorities, and others to ensure conformity of a medicine to MC standards through testing. The MC does not include standards for foods or for traditional medicines/dietary supplements. The MC is available at https://mc.usp.org.

**USP on Compounding: A Guide for the Compounding Practitioner**—USP on Compounding is an electronic compendium that includes all compounding-related general chapters from the USP–NF as well as the supporting general chapters that are referenced in the compounding general chapters and in USP–NF General Notices and Requirements. The purpose of USP on Compounding is to provide compounding practitioners with convenient access to associated general chapters.

**USP Herbal Medicines Compendium**—The USP Herbal Medicines Compendium (HMC) is an online compendium that will help ensure the quality of the herbal ingredients used in herbal medicines. HMC monographs provide quality specifications—tests, procedures, and acceptance criteria—with validated analytical procedures and allied reference materials that aid in conformity assessment. HMC can help ingredient manufacturers, herbal product manufacturers, regulatory agencies, and other stakeholders to assess conformance of herbal medicinal ingredients with independent public standards and to control the quality of articles moving in international commerce. The HMC is available at https://hmc.usp.org.

**USP Dietary Supplements Compendium**—The Dietary Supplements Compendium combines, in a two-volume set, USP–NF standards for dietary supplements, standards and information from the Food Chemicals Codex, regulatory and industry documents, and other tools and resources. It is published every two years as a hardcover print edition.

**Food Chemicals Codex**—The Food Chemicals Codex (FCC) is a compendium of internationally recognized monograph standards and tests for the purity and quality of food ingredients, e.g., preservatives, flavorings, colorings, and nutrients. FCC is published every two years, with supplements every six months, and is available in print and electronic formats. Proposed revisions to FCC are available for public viewing and comment through the FCC Forum. The FCC Forum can be accessed free of charge at forum.foodchemicals codex.org.

**OTHER USP RESOURCES**

**Chromatographic Columns**—This comprehensive reference, previously titled Chromatographic Reagents, provides detailed information needed to conduct chromatographic procedures found in USP–NF. Chromatographic Columns lists the brand names of the column reagents cited in every proposal for new or revised gas- or liquid-chromatographic analytical procedures that have been published in PF since 1980. Chromatographic Columns also helps to track which column reagents were used to validate analytical procedures that have become official. The branded column reagents list is updated bimonthly and maintained on USP's website.

**USP Dictionary**—The USP Dictionary of USAN and International Drug Names provides, in a single volume, the most up-to-date United States Adopted Names of drugs; official USP–NF names; nonproprietary, brand, and chemical names; graphic formulas; molecular formulas and weights; CAS registry numbers and code designations; drug manufacturers; and pharmacologic and therapeutic categories. The Dictionary helps to ensure the accuracy of the following: product labeling; reports, articles, and correspondence; FDA regulatory filings; and pharmaceutical package inserts. It is published annually. (See Nomenclature.)