



Guide to USP-Speak

Clear Definitions of
USP Terms and
Abbreviations for
Dietary Supplements
and Herbal Medicines
Stakeholders

This *Guide to USP-Speak* was developed specifically for USP dietary supplements and herbal medicines stakeholders. It is intended to foster a clear understanding of key terms, abbreviations, and acronyms used by USP staff when discussing USP dietary supplement and herbal medicine standards with stakeholders. This guide is provided only for informational purposes. It should not be construed as an official interpretation of USP compendial text, nor should it be relied on to demonstrate compliance with USP standards and requirements. We ask that stakeholders [provide feedback via email](#) to help us make necessary updates to this guide so that USP and our stakeholders can continue to effectively work together to accomplish our common goal of providing trusted, science-based, public quality standards to help safeguard the supply of dietary supplements and herbal medicines worldwide.

A handwritten signature in black ink, appearing to read 'G. Giancaspro', with a stylized flourish at the end.

**Gabriel I. Giancaspro, Vice President
Science–Dietary Supplements & Herbal Medicines**

Accelerated Revision Processes

Procedures for making revisions to the *United States Pharmacopeia–National Formulary (USP–NF)* and *Food Chemicals Codex (FCC)* faster than through the standard process. Accelerated Revisions do not necessarily require a public notice and comment period; they allow for a revision to become official or effective prior to the next scheduled publication. See also [Interim Revision Announcement](#) and [Revision Bulletin](#). Learn more about the [accelerated processes for revisions to the USP–NF](#) and the [FCC](#).

Admission Criteria, Dietary Supplement

Criteria USP uses to determine whether a dietary ingredient, as a component of a dietary supplement, qualifies for admission into the *USP–NF*. Learn more about [USP’s dietary supplement admission evaluation process](#).

Admission Evaluation, Dietary Supplement

USP’s evaluation of a dietary ingredient to help inform the USP Dietary Supplements Admission Evaluations Joint Standards-Setting Subcommittee determination as to whether to categorize the ingredient as Class A (admitted into the monograph development process) or Class B (not admitted into the monograph development process). Learn more about [USP’s dietary supplement admission evaluation process](#).

Balloting

Process by which USP documentary standards are presented to Expert Volunteers for review and approval using a ballot system prior to being published as official standards in the *USP–NF*, effective standards in the *FCC*, or authorized standards in the *Herbal Medicines Compendium (HMC)*. The suitability of USP Reference Standards for use with USP documentary standards is also approved by Expert Volunteers via ballot. Learn more about [USP’s standards-setting process](#).

Board of Trustees (BoT)

Makes decisions that guide USP’s policies, finances, and strategic direction. The BoT comprises two trustees who represent the medical sciences, two who represent the pharmaceutical sciences, one who represents the public interest, and three who serve in an at-large capacity. The officers include a president, treasurer, and past president. Learn more about the [USP BoT](#).

Botanical Drug Product

As defined by the U.S. Food and Drug Administration (FDA), a botanical drug product is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans. It consists of vegetable materials, which may include plant materials, algae, macroscopic fungi, or combinations thereof. It may be available as, but not limited to, a solution (e.g., tea), powder, tablet, capsule, elixir, topical, or injection. Botanical drug products often have unique features such as complex mixtures, lack of a distinct active ingredient, and substantial prior human use. Fermentation products and highly purified or chemically modified botanical substances are not considered botanical drug products. Learn more about how [FDA defines botanical drug products from FDA.gov](#).

Call for Candidates

An open invitation from USP asking qualified individuals to apply to serve as Expert Volunteers on Volunteer Bodies such as Expert Committees (ECs) or Expert Panels. Learn more about [USP’s Call for Candidates process](#).

Class A Dietary Ingredient (Admitted Into the Monograph Development Process)

Article for which the available evidence does not indicate a serious risk to health or other public health concern that would preclude admission of a quality monograph into the compendia. Learn more about [USP’s dietary supplement admission evaluation process](#).

Class B Dietary Ingredient (Not Admitted Into the Monograph Development Process)

Article for which the available evidence indicates a serious risk to health or other public health concern that precludes admission of a quality monograph into the compendia. Learn more about [USP’s dietary supplement admission evaluation process](#).

Code of Ethics

Guidance for USP staff and Expert Volunteers on how to carry out USP’s mission in compliance with the letter and spirit of applicable legal requirements, USP’s core values, and USP’s policies and processes. Learn more about [USP’s Code of Ethics](#).

Commentary

Summary of an EC's responses to public comments received on revisions to documentary standards proposed in the *Pharmacopeial Forum (PF)* or *FCC Forum*. Learn more about the [commentary process for the USP–NF](#) and [FCC](#).

Commenter

Individual or organization that submits information on a documentary standard proposed in the *PF* or *FCC Forum*. Learn more about [commenting on USP proposed standards](#).

Comment Period, Public

Typically, 90 days during which stakeholders are encouraged to comment on proposed or revised monographs and general chapters for consideration by the relevant ECs. Learn more about the [USP standards-setting process](#).

Comment, Public

Process through which a newly proposed or revised compendial documentary standard is publicly presented in the *PF* or *FCC Forum* for stakeholder review and comment. Learn more about [commenting on USP standards](#) and [providing input for HMC monographs](#).

Compendial Standards

Public standards issued in USP compendia as official, authorized, or effective text. Learn more about [USP's compendial standards](#).

Convention Membership

Member organizations and their delegates (from academic institutions, health practitioner and scientific associations, consumer organizations, manufacturer and trade associations, government bodies and associations, and non-governmental standards-setting and conformity assessment bodies) that participate in discussions on issues important to their constituents and carry out critical USP governance activities. See also [USP Governance](#). Learn more about the [USP Convention membership](#).

Council of Experts (CoE)

Volunteer body composed of the Chairs of individual ECs elected by the USP Convention membership; it is one of three USP governing bodies. See also [USP Governance](#). Learn more about the [USP CoE](#).

Council of Experts (CoE) Chair

Establishes policies and work plans, assigns responsibilities, and otherwise directs the work of the CoE, its ECs, USP staff, and other subsidiary groups. Learn more about [USP's leadership](#).

Cycle

USP's five-year cycle in advance of which the Expert Committee Chairs (i.e., the CoE) and BoT are elected by the Convention, and major resolutions are passed to set the strategic direction for USP activities. Learn more about [USP's five-year cycle](#).

Delayed Implementation of Documentary Standard

Designated period of time added by an EC to the typical six-month implementation period that allows stakeholders sufficient time to achieve compliance without being unduly burdened; typically determined following stakeholder input and in consultation with regulators. Learn more about [compliance with the USP–NF](#) and the [FCC](#).

Dietary Ingredient

As defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act), a "dietary ingredient" is any one of the following: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in (A), (B), (C), (D), or (E). Learn more about [how the FD&C Act defines dietary ingredients from GPO.gov](#).

Dietary Supplement Health and Education Act (DSHEA) of 1994

Legislation that amended the FD&C Act, thereby creating a new regulatory framework for the safety and labeling of dietary supplements. Learn more about [DSHEA from FDA.gov](#).

Dietary Supplements Compendium (DSC)

Quality standards provided to manufacturers and others to ensure the identity, potency, and purity of dietary supplement products. This publication includes documentary standards from the *USP–NF* and *FCC*, as well as admission evaluation reviews, illustrations, industry and regulatory guidance documents, supplemental information, and reference tools. Learn more about the [DSC](#).

Dietary Supplements e-Newsletter

Information provided to the dietary supplements community on USP’s activities; proposed monographs, general chapters, and USP Reference Standards; and services. Learn more about [USP’s Dietary Supplements e-Newsletter](#).

Documentary Standards

Publicly available written quality standards for ingredients and finished products in the *USP–NF* and *FCC* that in many cases link directly with USP Reference Standards. Learn more about [USP Standards](#).

Donors

Organizations that contribute data and material to support the development of new or modernized monographs and candidate reference materials intended for use as public standards. See also [sponsors](#). Learn more about [USP’s Donor Recognition Program](#).

Elemental Contaminants

Elemental substances (such as arsenic, cadmium, lead, mercury) that may be present in a dietary ingredient or dietary supplement. USP standards require limits on the levels of these contaminants. Learn more about [elemental contaminants](#).

Errata

Text erroneously published in the *USP–NF* or its *Supplements* that does not accurately reflect the intended requirements as approved by the CoE. Errata are posted to ensure that *USP–NF* users receive information about them in a timely manner. Learn more about [how USP handles errata](#).

Expert Committee (EC)

Scientific decision-making volunteer body, composed of Expert Volunteers, ultimately responsible for the approval of USP standards (i.e., monographs, general chapters, and associated Reference Standards). Each EC presides over a specific set of standards within the area of its specific competency. The primary USP staff contact for an EC is the Scientific Liaison. Learn more about [ECs](#).

Expert Committee, Botanical Dietary Supplements and Herbal Medicines (BDSHM)

Develops and revises monographs, general chapters, and USP Reference Standards for botanical dietary supplement ingredients and products; and herbal medicine ingredients, powders, and extracts. Learn more about the [BDSHM EC Work Plan](#).

Expert Committee Chairs

Elected by the USP Convention membership at its regular meeting held every five years. Each Chair serves a five-year term or until a successor is installed in the event of a vacancy, and is an ex officio member of the CoE. Learn more about [EC Chairs](#).

Expert Committee, Non-Botanical Dietary Supplements (NBDS)

Develops and revises monographs, general chapters, and USP Reference Standards for vitamins, minerals, amino acids, marine and terrestrial plant-derived oils, probiotics, and other specialty ingredients. Learn more about the [NBDS EC Work Plan](#).

Expert Panel

An advisory—not decision-making—body formed to provide additional expertise on a particular compendial topic and provide recommendations to one or more ECs or the CoE. Expert Panels have a specific charge and are dissolved at the conclusion of their work. USP calls for Expert Panel candidates as the need for such bodies arises. Learn more about [Expert Panels](#).

Expert Volunteer

Subject matter experts from industry, government, healthcare, academia, or other relevant sectors who volunteer to serve on the CoE, ECs, and/or Expert Panels. Learn more about [Expert Volunteers](#).

Federal Food, Drug, and Cosmetic Act (FD&C Act)

A federal law enacted by Congress codified into United States Code (U.S.C.) Title 21, Chapter 9. Learn more about [the FD&C Act from GPO.gov](#).

Food Chemicals Codex (FCC)

Compendium of internationally recognized standards for the purity and identity of food ingredients. It contains monographs for food-grade chemicals, processing aids, foods, flavoring agents, vitamins, functional food ingredients, and ingredients. Learn more about the [FCC](#).

Food Chemicals Codex Forum

Online publication that provides the opportunity for public review and comment on new additions to, and revisions of, *FCC* content. Learn more about the [FCC Forum](#).

Food Fraud Mitigation Guidance (FFMG)

Framework to help companies identify vulnerabilities in their ingredient supply chains and implement control plans that mitigate risks. Learn more about [USP's FFMG](#).

General Chapter

General conceptual and procedural guidance for *USP-NF* monographs; frequently contains tests and procedures referred to in multiple monographs. Learn more about [USP General Chapters and other USP-NF components](#).

General Chapter Prospectus

Brief statement about new general chapters or major general chapter revisions, provided prior to their publication in the *PF*, to solicit advisory input during the early stages of development. Learn more about the [general chapter prospectus process](#).

Government Liaison (GL)

Representative from the FDA or other federal, state, or foreign government agency who contributes to discussions from the perspective and on behalf of the government agency, offers opinions on all facets of standards development, and may be charged with seeking further information or soliciting opinions from the agency they represent. GLs do not vote on standards that are up for ballot. Learn more about [how USP and FDA work together](#).

Harmonization

The process through collaborative effort whereby differing requirements among participating "authorities" move toward alignment on common requirements that yield the same outcome. Learn more about [harmonized standards](#).

Herbal Medicine Compendial Articles

Herbal ingredients in their entire and processed forms (e.g., powders, extracts, fractions) that are approved by a national authority outside of the U.S. for use as ingredients of herbal traditional medicines or are included in a national pharmacopeia and deemed appropriate for inclusion in the *HMC*. Learn more about [HMC monographs](#).

Herbal Medicines Compendium

An online resource that provides standards for herbal ingredients used in herbal medicines. Standards are expressed primarily in monographs that provide the definition of an herbal ingredient along with the validated analytical procedures and acceptance criteria for specified tests using state-of-the-art analytical techniques and allied reference materials. Learn more about the [HMC](#).

Interim Revision Announcement (IRA)

Type of Accelerated Revision that provides an expedited mechanism for making revisions official. After a 90-day notice and comment period and approval by the relevant USP EC, IRAs are posted as official text on USP.org and incorporated into the next published *USP-NF* or *Supplement*. See also [Accelerated Revision Processes](#) and [Revision Bulletin](#). Learn more about [IRAs](#).

Joint Standards-Setting Subcommittee (JS3)

Volunteer body composed of EC members from at least two ECs. It is authorized to develop and approve compendial standards. For example, the Dietary Supplements Admission Evaluations JS3 determines whether USP should develop monographs for specific articles. Learn more about [JS3s](#).

Monograph

Compendial compilation of specifications and analytical procedures used to define a specific pharmacopeial article, typically including packaging and labeling requirements. Monographs provide tests, methods, and acceptance criteria to define the identity, composition, and limits of contaminants of the compendial article. Learn more about [USP monographs](#).

Monograph Modernization (Also Called Up-to-Date)

The process by which monographs are revised to replace outdated methodology with more contemporary procedures. Learn more about [monograph modernization](#).

New Dietary Ingredient (NDI)

FDA defines an NDI as “a dietary ingredient that was not marketed in the U.S. before October 15, 1994 (21 U.S.C. 350b(d)). Thus, to be an NDI, a substance must be a dietary ingredient.” Learn more about [NDIs from FDA.gov](#).

New Dietary Ingredient Notification (NDIN)

Premarket safety notification from the manufacturer or distributor of an NDI submitted to FDA at least 75 days before the article is introduced into interstate commerce. Learn more about [NDINs from FDA.gov](#).

Nomenclature Guideline, Dietary Supplements and Herbal Medicines

Guideline that sets forth systems USP uses to assign titles to monographs for dietary supplements and herbal medicine ingredients that are published in the *USP–NF*, *DSC*, and *HMC*. Learn more about the USP [Guideline for Assigning Titles to USP Dietary Supplement Monographs](#).

Observer

Individual who requests permission to attend an open official EC, Expert Panel, or JS3 meeting and whose participation is subject to the current *Rules and Procedures of the Council of Experts*. Learn more about [observing an EC meeting](#).

Official Date

Date that a new or revised *USP–NF* standard becomes official, typically six months after its release or posting date, unless otherwise indicated. Learn more about [USP’s six-month Implementation Guideline](#).

Official Standard/Text

Legally enforceable text included in the *USP–NF* or its *Supplements*. Learn more about [USP’s standards-setting process](#).

Omission

Standard that is omitted from a USP compendium. USP may propose to omit a monograph from the *USP–NF* if the article is no longer marketed in the U.S. and serves no public health need. Monographs may also be proposed for omission from the *FCC* because of safety concerns. Learn more about [USP’s expanded monograph omission initiative](#).

Orthogonal Method

An added method that uses fundamentally different principles to improve confidence in testing. For example, adding chromatographic peak identification to an infrared (IR) identification test. Learn more about orthogonal methods from USP papers published in [Drug Testing and Analysis](#) and [Phytomedicine](#).

Pharmacopeia

Collection of officially recognized standards for drugs, ingredients, dietary supplements, and herbal and/or other medicinal preparations. Learn more about the [USP–NF](#).

Pharmacopeial Forum (PF)

Free bi-monthly online publication that presents proposals for new or revised *USP–NF* standards for public review and comment before comments are evaluated and proposals are approved by ECs. Learn more about the [PF](#).

Plant Processed Forms

Plant material that has been subjected to processing (e.g., grinding to powder). Examples include juices, powders, extracts, and fractions, but do not include isolated pure compounds. Learn more about [plant processed forms](#).

Raw Material

Any ingredient intended for use in the manufacturing of a dietary ingredient or dietary supplement, including those that may not appear in the finished product. (A dietary ingredient is a raw material when considering the manufacture of a dietary supplement.) Learn more about raw materials in [General Chapter <2750> Manufacturing Practices for Dietary Supplements](#) (requires paid subscription).

Reference Standard (RS)

Extensively characterized material with well-defined physical and chemical properties that may be used in compendial applications. Learn more about [RSs](#).

Residual Solvents

Organic volatile chemicals that are used or produced in the manufacturing of drug substances, excipients, or dietary ingredients, or in the preparation of drug products or dietary supplement products. Learn more about [residual solvents](#).

Resolutions

Statements adopted by the USP Convention membership that provide overarching guidance for USP during each five-year cycle and are reflected in USP's policy and operational agendas. Learn more about [Resolutions](#).

Revision Bulletin (RB)

Type of Accelerated Revision intended to address substantive issues that have broad impact including urgent patient safety or compliance issues. Posted on USP.org without public comment, an *RB* replaces the entire published monograph, including the specified change, and is incorporated into the next published *USP–NF* or *Supplement*. See also [Accelerated Revision Processes](#) and [Interim Revision Announcement](#). Learn more about [RBs](#).

Revision Process, Standard

Addition of new or revised text to documentary standards by publishing a proposal for public comment, and then adopting it as official content upon approval by the relevant EC. Learn more about the [USP standards-setting process](#).

Revision Proposal

Text published in the *PF* or *FCC Forum* that requires EC approval before becoming official or effective. The text could be a new monograph or general chapter, updates to an existing monograph or general chapter, or an addition or revision to the General Notices and Requirements, the official text that provides the foundational assumptions, definitions, interpretation, and application of the *USP–NF*. Learn more about the [USP standards-setting process](#).

Scientific Liaison (SL)

USP scientific staff responsible for the development and maintenance of compendial content. Learn more about [Dietary Supplements and Herbal Medicines scientific staff](#).

Sponsors

Organizations that submit data for new or revised *USP–NF* monographs and reference material development to USP. Also called [donors](#). Learn more about [sponsors and donors](#).

Stakeholders

Individuals belonging to industry, government, academia, or pharmacopeial or other relevant sectors whose function is affected by or reliant on USP scientific output, including documentary and/or Reference Standards. Learn more about [USP Stakeholder Forums](#).

Standard Common Name (SCN)

Usual name of a botanical (including fungi and algae) dietary ingredient as standardized in *Herbs of Commerce* published by the American Herbal Products Association. Learn more about the USP [Guideline for Assigning Titles to USP Dietary Supplement Monographs](#).

Standards-Setting Process

Continuous revision process that typically includes submission, development, and posting of a proposed new or revised standard for public comment; EC review of public comments, balloting, and approval; and publication in a USP compendium. Learn more about the [USP standards-setting process](#).

Stimuli Article

Article published in the *PF* on standards-related topics to solicit public input. Learn more about [PF and Stimuli articles](#).

Submission Guidelines

Guidelines on how to submit information to support the development of a new or revised *USP–NF* or *FCC* monograph. Learn more about [submission guidelines](#).

United States Pharmacopeia and National Formulary (USP–NF)

Combination of two compendia, the *United States Pharmacopeia (USP)* and the *National Formulary (NF)*. The *USP* features monographs for drug substances, dosage forms, and compounded preparations, as well as a separate section for dietary supplement and ingredient monographs. The *NF* features excipient monographs. Learn more about the [USP–NF](#).

USP

Acronym for the independent, scientific, nonprofit organization also known as the United States Pharmacopeial Convention. USP's mission is to improve public health by setting quality standards and related programs for medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide. Learn more about [USP](#) and [our new brand identity](#).

USP Governance

Three governing bodies composed entirely of volunteers from around the world: the USP Convention membership, which includes standing committees (i.e., the Council of the Convention and Convention Governance Committee); the BoT; and the CoE (and its ECs). Learn more about [how USP is governed](#).

USP Reference Standard Certificate

Certificate issued with a USP Reference Standard to provide a written copy of the label text, molecular information, typical chromatograms, and additional use/handling information that is not on the Reference Standard label. Learn more about [USP Reference Standard Certificates](#).

USP Verification Services

Include programs aimed at verifying the quality of ingredients and products. USP annually evaluates the quality of verified products through the three-step process of Good Manufacturing Practice (GMP) facility audits, product quality control & manufacturing (QCM) process evaluation, and product testing. The USP Verification Services' multi-step process provides increased confidence in supplier qualification, multiple snapshots of the quality management system, and product testing that helps manufacturers maintain an edge in an increasingly competitive global market. Learn more about [USP Verification Services](#).

Volunteer Body

Group of Expert Volunteers participating in USP's standards-setting process (e.g., CoE, EC, Expert Panel, or JS3). Learn more about [USP volunteer bodies](#).

Work Plan

Document or webpage that sets forth the EC's goals and objectives for a five-year cycle. Learn more about [USP EC Work Plans](#).