USP Guideline on Use of Accelerated Processes for Revisions to the *USP-NF and FCC*[1]

Background

The Rules and Procedures of the Council of Experts (Rules) specify various processes (Accelerated Revision Processes) that can be used to make revisions to the *United States Pharmacopeia* and the *National Formulary (USP–NF)* official[1] and to the *Food Chemicals Codex* (FCC) effective[2] more quickly than through USP's standard process (Standard Revision Process). USP's Standard Revision Process calls for publication of a proposed revision in the *Pharmacopeial Forum (PF)* or *FCC Forum* 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, FCC,* or their *Supplements*, as applicable. Accelerated Revision Processes include *Errata, Interim Revision Announcements*, and *Revision Bulletins for the USP–NF*; and *Errata, Expedited Standards*, and *Immediate Standards* for the *FCC.* Also discussed in this Guideline are changes made via Compendial Notices, such as Reference Changes. Accelerated Revisions do not always require publication in *PF* and allow for a revision to become official or effective prior to the next *USP–NF*, *FCC*, or *Supplement* thereto.

The purpose of this Guideline is to delineate the circumstances under which these Accelerated Revision Processes and Compendial Notice Reference Changes are utilized. The Decision Tree that follows specifies the criteria that are applied by USP in considering whether an Accelerated Revision Process is appropriate rather than USP's Standard Revision Process. The footnotes to the Decision Tree provide additional explanations for applying the criteria outlined in the Decision Tree, and further clarification as to when an Accelerated Revision Process rather than the Standard Revision Process should be utilized.

Definitions

***Errata* (*USP–NF* and *FCC*)**—An *Erratum/Errata* published in the errata table is erroneously published content in a USP compendium that does not accurately reflect the intended requirements of a standard as approved by the responsible Expert Committee. Errata published in the errata table are errors, clarifications, or missing information such as inaccuracies in chemical formulas, mathematical equations relevant to analyses and/or inaccurate descriptions of the apparatus, or materials used to perform analytical tests. Typically Errata are changes that do not have a broad impact on the standard. *Errata* are not subject to public notice and comment. *Errata* published on the USP website become official/effective on the first day of the month following publication. *Errata* are incorporated into the next available *USP–NF*, *FCC*, or *Supplement* thereto.

***Interim Revision Announcements (IRAs)* (*USP–NF*)**—*IRAs* are an expedited mechanism for making revisions official. An *IRA* appears in *PF* first as a *Proposed Interim Revision Announcement* with a 90-day comment period.[3] If there are no significant comments, the *IRA* becomes official in the "Official Text" section of the USP website, with the official date indicated. *IRAs* replace the entire published

[1] Official: An official article is an article that is recognized in *USP* or *NF*. An article is deemed to be recognized and included in a compendium when a monograph for the article is published in the compendium and an official date is generally or specifically assigned to the monograph. (General Notices and Requirements Section 2.20)

[2] Effective: After approval by the Food Ingredients Expert Committee, an *FCC* proposal shall be published in the next edition of the *FCC* or *Supplement* thereto, as applicable, and shall become effective 90 days from the date of publication unless otherwise provided. Items published in the *FCC* are given effective dates and are not consider official *USP-NF* text.

[3] Prior to PF 37(1), IRAs were available for comment for 60 days.

monograph including the specified change and are incorporated into the next available *USP–NF* or *Supplement*.

***Revision Bulletins* (*USP–NF*)**—If circumstances require rapid publication of official text, a revision or postponement may be published through a *Revision Bulletin*. *Revision Bulletins* are posted on the USP website with the official date indicated. *Revision Bulletins* replace the entire published standard including the specified change and are incorporated into the next available *USP–NF* or *Supplement*.

Expedited Standards (FCC)—If the Food Ingredients Expert Committee (FI EC) determines that for public health or other appropriate reasons, a new or revised standard should be made available prior to publication of the next edition of the *FCC* or *Supplement*, it may be posted as final on the USP website following notice and comment and approval by the FI EC. An *Expedited Standard* will be effective upon website publication after the 90-day comment period, unless a delayed effective date is specified therein. Upon publication of the next edition of the *FCC* or *Supplement* thereto, as applicable, any *Expedited Standard* that has become effective since publication of the last edition or *Supplement* will be included in such volume and removed from the USP website.

Immediate Standards (FCC)— In those rare cases where the FI EC determines that a new or revised standard should be made available immediately because of an urgent public health need, a standard may be approved by the FI EC and posted as final on the USP website without the notice and comment period specified above. An *Immediate Standard* will be effective upon website publication, unless a delayed effective date is specified therein. Upon publication of the next edition of the *FCC* or *Supplement* thereto, as applicable, any *Immediate Standard* that has become effective since the last edition or *Supplement* will be included in such volume and removed from the USP website.

Compendial Notice (*USP–NF*)—Reference Changes represent an example of changes made via Compendial Notice. Sometimes it is necessary for USP to modify general chapter titles, appendix titles, references to external resources, or similar text that may be referenced in standards throughout the *USP–NF*. Any reference changes that will have an impact on the interpretation or requirements of the standard are made using the routine revision process including publication for comment in *PF*. In cases in which an update appears to present no significant change in the affected standard, they are implemented through a direct update of the reference in that standard without providing an opportunity for notice and comment.

In these cases, USP will publish on its website a Compendial Notice (CN) indicating the source change and any resulting references. Updates made through direct publication in the *USP–NF* will be clearly identified by symbols and shading in the print and electronic publications.

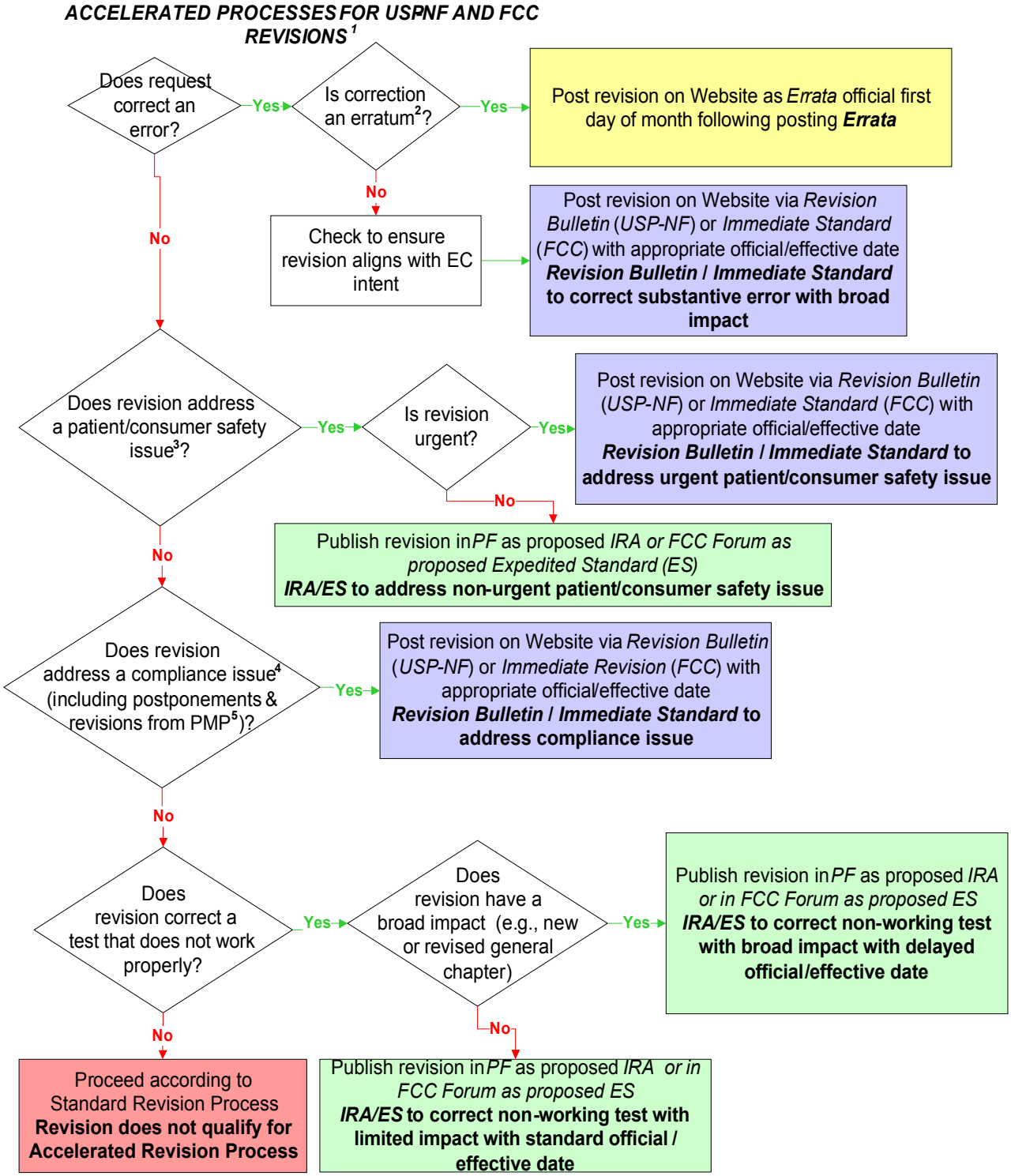
Because some updates to references may be assigned delayed official dates to ensure that all related revisions become official together, the revision markup used to identify the reference updates will be dependent upon when the change will become official. Updates becoming official at the same time as the *USP–NF* in which they are published will be identified with the following revision markup, where CN denotes Compendial Notice:

▲
Changed text ▲ (CN 1-May-2019)

Updates becoming official/effective on a future date than the *USP–NF* in which they are published will be identified with the following revision markup:

▲
Changed text ▲ (Official 1-May-2019)

Accelerated Revision Decision Tree



USP Guideline on Use of Accelerated Processes for Revisions to the *USP-NF and FCC*[1]

Notes and References on Decision Tree

1. **General**
   a. Revisions to the *USP–NF or FCC* (whether new monographs or general chapters/tests or changes to existing monographs or general chapters/tests) generally are made through the Standard Revision Process unless the revision falls into one of the categories listed in the Accelerated Revision Process Decision Tree.
   b. To the extent possible, changes resulting from the Pharmacopeial Discussion Group (PDG) harmonization process are made through the Standard Revision Process.
   c. *Revision Bulletins* and *Immediate Standards* generally are posted on the USP website on the last Friday of every month with an appropriate official/effective date. *Revision Bulletins* and *Immediate Standards* that address an urgent patient/consumer safety issue as described in Paragraph 3 below may be posted at any time. These *Revision Bulletins* or *Immediate Standards*, or those that address a compliance issue as described in Paragraph 4 below may become official/effective immediately.
   d. *Notices of Intent to Revise*: USP may issue a Notice of Intent to Revise (NITR) to alert manufacturers to the upcoming revision to a proposed or official standard. The NITR will be posted on the Compendial Notices section of the *USP–NF* or *FCC* website. NITR can be utilized for revisions made via an Accelerated Revision or through the Standard Revision Process.

2. **Correction of Errors**
   a. *Errata* are corrections to items erroneously published that do not accurately reflect the intended official/effective requirements as approved by the responsible Expert Committee. These typically are minor changes that are fairly obvious and do not have a broad impact.
   b. Errors that are more substantive and do have a broad impact (such as those that impact test method instructions, solution preparations, etc. and require change control to implement) are not considered *Errata*. These errors are corrected using *Revision Bulletins or Immediate Standards* with appropriate official/effective dates.

3. **Safety-related Revisions**
   a. Urgent safety-related revisions are handled as *Revision Bulletins or Immediate Standards,* with an appropriate official/effective date, which can sometimes be immediate. The official/effective date should be determined based on level of safety concerns, significance of change, and/or potential implementation issues, etc. *Interim Revision Announcements* and *Expedited Standards* are used to effectuate non-urgent safety-related revisions.
   b. Prior to posting a *Revision Bulletin* or *Immediate Standard* for an urgent safety-related revision, USP will, as feasible and appropriate given the safety issue involved and impact of the proposed revision, obtain stakeholder input through expedited and informal processes.

c. USP will consider the impact of the safety-related revision in determining the approach used to address the safety issue (speed of method development, ease of implementation in industry) and the timing of the official/effective date after publication.

4. **Compliance-related Revisions**
   a. In order to qualify for a *Revision Bulletin* or *Immediate Standard*, a compliance-related revision cannot create a compliance issue for other stakeholder.
   b. Postponement of official date: If a *USP–NF* requirement has been published that will have the effect of putting all or a substantial part of the pharmaceutical industry out of compliance, then the use of a *Revision Bulletin* that postpones the official date of such requirement until compliance can reasonably be achieved is appropriate. This *Revision Bulletin* will have an immediate official date, and may be posted outside of the normal Revision Bulletin posting schedule.
   c. Compliance Issues: If a *USP–NF* requirement has been published for a specific article for which a company has an approved application with FDA but the compendial requirement is in conflict with the application requirement, then a revision or retraction of the compendial requirement via a *Revision Bulletin* with an immediate official/effective date can be used to ensure the company is not out of compliance. Additional compliance-related revisions for products without an approved application with FDA (e.g., OTCs monograph drugs, Food Ingredients, and Dietary Supplements) can be considered on case-by-case basis.
   d. Flexible Monographs: USP can utilize a flexible monograph approach using a *Revision Bulletin* or *Immediate Standard* to resolve a compliance issue for a company. These *Revision Bulletins* or *Immediate Standards* will have an immediate official date. Examples of such revisions are the inclusion of multiple procedures (e.g., Test 2) for dissolution or impurities in a monograph or adding a new hydrate/polymorphic form and associated specifications. *Interim Revision Announcements* are typically used for inclusion of an additional procedure for impurities in a monograph, to provide an opportunity for public comments.

5. **Pending Revisions (*USP–NF*)**: Revisions proposed under the Pending Monograph Program (PMP) become official via *Revision Bulletin.* For more information and details on the Pending Monograph Program please see Pending Monograph Guideline and FAQs on this topic.

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Revision History

Version G01.01-01

Section: Various
Changes:

- Incorporated description of Reference Changes in the *Guideline*. Included note that changes made to accommodate external reference changes may also use the Compendial Notices Reference Change process.

- Added a note that compliance-related revisions can be made to accommodate sponsors of non-FDA approved products on a case-by-case basis.
- Combined discussion of *USP-NF* and *FCC* Accelerated Revisions into one guideline. Previously, there was a separate guideline for *FCC* Accelerated Revisions, G1.02-00. The contents of this document were added to G1.01-00. G2.01.00 will be retired once G1.02 is effective.
- Added footnote and information in decision tree regarding handling of *Revision Bulletins* from the Pending Monograph Program.
- Revised description of *Errata* to match current USP definition in the *Errata* SOP and remove specification the *Errata* can only be made on official text.
- Indicated that the *Revision Bulletins/Immediate Standards* are typically posted on the last Friday of the month, previously Revision Bulletins were scheduled to be posted every other month.
- Updated decision tree diagram to reflect incorporation of *FCC* revisions and reference to note about Pending Monograph Program.
- Deleted the footnote pertaining to the Authorized Pending Monographs.

Version G1.01-00 August 1, 2015

Document number added and document routed through document control. No changes to Guideline content.

Version 3.1, Effective March 6, 2014

Section: Various
Change: Updated template and made minor editorial corrections.

Version 3.0, Effective August 31, 2012

Section: Footnotes for Decision Tree
Change: Specify that Revision Bulletins typically are posted every other month, but may be posted at any time to address an urgent need.

Version 2.1, Effective August 1, 2011

Section: Definitions and Decision Tree
Change: Revised definition of Errata and changed official date of Errata from immediately when published to the first day of the month following publication.

Version 2.0, Effective September 1, 2010

Section: Background
Change: Removed the reference to the obsolete document *The Rules and Procedures of the 2005-2010 Council of Experts*

Removed sentence: “this Guideline addresses the use of delayed official dates for revisions made through the Standard Revision Process where such revisions have broad industry impact and require additional time to implement.”

Section: Definitions
Change: Created section.

Section: Decision Tree
Change: Removed numbers from each scenario, removed reference to *Errata* appearing in *Pharmacopeial Forum* (*PF*) due to the change to the all-online *PF* in January 2011, and made minor editorial changes.

Section: Decision Tree
Change: Removed Standard Revision Process Decision Tree because delayed implementation for Standard Revisions is not related to the Accelerated Revision Process.

Section: Footnotes for Decision Tree, General, Paragraph 1c
Change: Clarified that generally *Revision Bulletins* will be posted on the last Friday of the month and that *Revision Bulletins* intended to address urgent safety-related revisions or compliance issues may become official immediately

Section: Footnotes for Decision Tree, General, Paragraph 1d (new)
Change: Added a provision that USP may issue a "Notice of Intent to Revise" to alert manufacturers to the upcoming proposal

Section: Footnotes for Decision Tree, Correction of Errors, Paragraph 2a
Change: Changed "Council of Experts" to "particular Expert Committee" to be consistent with the Decision Tree.

Section: Footnotes for Decision Tree, Safety-related revisions, Paragraph 3a
Change: Clarified that *Revision Bulletins* for urgent safety-related revisions will have an appropriate official date which can be immediate

Section: Footnotes for Decision Tree, Compliance-related revisions, Paragraph 4a
Change: Added a provision that a *Revision Bulletin* created to address a postponement of an official date may be posted outside of the normal *Revision Bulletin* posting schedule

Section: Footnotes for Decision Tree, Compliance-related revisions, Paragraph 4b
Change: Clarified that if a *USP-NF* requirement has been published for a specific article for which a company has an approved application with FDA but that company cannot meet the requirement, then a revision of that requirement via a *Revision Bulletin* with an immediate official date can be used to ensure the company is not out of compliance. Added the term "retraction" to the above sentence after the word "revision" because at times revisions are retracted by USP.

Section: Footnotes for Decision Tree, Compliance-related revisions, Paragraph 4c
Changes: Added a provision that a *Revision Bulletin* created to solve a compliance issues will have an immediate official date; replaced the term "related compounds" with "impurities" in the final sentence to indicate the inclusion of "multiple procedures" for dissolution or impurities in a monograph.

Version 1.0, Effective December 1, 2008
Initial version

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