Commentary
***Food Chemicals Codex* (*FCC*)**
Ninth Edition

February 28, 2014

In accordance with USP's Rules and Procedures of the 2010-2015 Council of Experts, and except as provided in Section 8.01(e) Immediate Standards, USP publishes proposed revisions to the *Food Chemicals Codex (FCC)* for public review and comment in the *FCC Forum* (*FCCF)*, USP's journal for public notice and comment for *FCC*. After comments are considered and incorporated as the Food Ingredients Expert Committee (FIEC) deems appropriate, the proposal may advance to official status or be republished in *FCCF* for further notice and comment, in accordance with the Rules and Procedures. In cases when proposals advance to official status without republication in *FCCF*, a summary of comments received and the FIEC's responses are published on the *Commentary* section of the USP Website at the time the revision is published.

The *Commentary* is not part of the text of the monograph or general test or assay. Rather, it explains the basis of the FIEC's response to public comments. If there is a difference between the contents of the *Commentary* section and the monograph or general test or assay, the text of the monograph prevails. In case of a dispute or question of interpretation, the language of the monograph text, alone and independent of the *Commentary* prevails.

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Comments were received for the following when they were proposed in the Food Chemicals Codex Forum (FCCF):

Monographs:

Allyl Mercaptan
Beta-Carotene
Bisabolene
Butyl Stearate
Glycine
Insoluble Foreign Matter in Amino Acids
L-Arginine
L-Glutamic Acid
L-Glutamine
L-Isoleucine
L-Leucine
L-Lysine Monohydrochloride
L-Methionine
L-Valine
Sodium Hyaluronate (From Microbial Fermentation)
Sulfur
Xylose
Zein
Zinc Acetate
Zinc Stearate

No Comments were received for the following when they were proposed in the Food Chemicals Codex Forum (FCCF):

Monographs:

Brilliant Black PN
Calcium Chloride
Calcium Saccharin
Copper Limit Test
Diatomaceous Earth
Glucoamylase Activity (Amyloglucosidase Activity)
Polyethylene Glycols
Potassium Phosphate, Dibasic
Sodium Saccharin
Spirulina

Monograph/Section(s): Allyl Mercaptan/Assay
Expert Committee(s): Monographs–Food Ingredients
Expert Committee initiated Change #1: The Expert Committee replaced the words “reference standard” with “reference material” in the *Reference Standards* for *Assay* in order to distinguish between USP reference standards and those sourced elsewhere.

Monograph/Section(s): Beta-Carotene/Multiple Sections
Expert Committee(s): Monographs–Food Ingredients
No. of Commenters: 3
Comment Summary #1: The commenters requested that the following sentence be added to the *Description*: “It consists predominantly of all-*trans*-β-carotene, but may also contain minor amounts of *cis*-isomers and other carotenoids.” The commenter indicates that this statement might be helpful to users as it indicates the main isomer present.
Response: Comment incorporated with changes. The Committee added the parenthetical phrase “see specifications” to the end of the sentence to indicate that the amounts of other isomers allowed in the product are dictated by the monograph specifications.
Comment Summary #2: The commenters requested that the *Description* section be revised to add “water-dispersible emulsions” to the list of commercially available forms of this ingredient already included in the *Description* to accurately reflect all product types available.
Response: Comment incorporated.
Comment Summary #3: The commenters requested that absorbance wavelength be changed from 457 nm to 455 nm in the Analysis section of the *Assay* for *Total Carotenoids*. This change was requested in order to harmonize with the *Acceptance criteria* from *Identification* test *A* where 455 nm is indicated as the approximate wavelength of maximum absorption.
Response: Comment incorporated.
Comment Summary #4: The commenter requested a variety of changes to the *Assay* for *β-Carotene* that would harmonize that test method with their own internal procedures.
Response: Comment not incorporated. The Expert Committee will consider proposing a revision in an upcoming *FCC Forum* if appropriate data is received to support the request.
Comment Summary #5: The commenter requested that the relative response factor for all-*trans*-alpha-carotene be changed from 1.1 to 0.95 in the test for *Alpha-Carotene and Other Related Compounds*.
Response: Comment not incorporated. The Expert Committee will consider proposing a revision in an upcoming *FCC Forum* if appropriate data is received to support the request.
Comment Summary #6: The commenter requested that the equation in the test for *Alpha-Carotene and Other Related Compounds* be changed so that the denominator incorporates all related compounds into r_T. The description of the variables in the equation would also be changed so that r_T includes the “sum of

(peak area x relative response factor) for all-*trans*-alpha-carotene, all-*trans*-beta-carotene, 9-*cis*-beta-carotene, 13-*cis*-beta-carotene, and 15-*cis*-beta-carotene. The relative response factors are obtained from Table 1."
Response: Comment incorporated.
Expert Committee Initiated Change #1: The Expert Committee changed the test for *Lead* in the *Inorganic Impurities* section from *Lead Limit Test, Atomic Absorption Spectrophotometric Graphite Furnace Method, Method I, Appendix IIIB* to *Lead Limit Test, Flame Atomic Absorption Spectrophotometric Method, Appendix IIIB*. The test name appearing in the *FCC Forum* was erroneous and should not have changed from the previous version. This change reinstates the correct test title and Appendix reference.
Expert Committee Initiated Change #2: The Expert Committee changed the title of *B. Visible Absorption Spectrum* in *Identification* test to *B. Absorbance Ratio* because the test does not require a full spectrum.

Monograph/Section(s): Bisabolene/Description
Expert Committee(s): Monographs–Food Ingredients
No. of Commenters: 1
Comment Summary #1: The commenter indicated that the chemical name listed in the Description for the alpha-isomer of Bisabolene, "(Z)-1-Methyl-4-(6-methylhept-5-en-2-ylidene)cyclohex-1-ene (alpha-bisabolene)" is incorrect and that the correct name is "(E)-1-Methyl-4-(6-methylhepta-2,5-dien-2-yl) cyclohex-1-ene."
Response: Comment incorporated.

Monograph/Section(s): Butyl Stearate/Identification
Expert Committee(s): Monographs–Food Ingredients
Expert Committee initiated Change #1: The Expert Committee added the *GC Peak Identity* test with *Acceptance criteria* in the *Identification* test to provide additional means of identification.

Monograph/Section(s): Insoluble Foreign Matter in Amino Acids, Appendix IIC
Expert Committee(s): Monographs–Food Ingredients
No. of Commenters: 1
Comment Summary #1: The commenter requested changing the proposed methodology for insoluble impurities to that appearing in USP <788> *Particulate Matter in Injections*, Method 2: Microscope Particle Count Test. The commenter indicates that the method proposed in the *FCC* proposal has the possible problem that foreign matters can be lost when drying or moving the filter cloth. They also indicated that their suggested alternative methodology has been adopted by the U.S. Pharmacopeia, the European Pharmacopoeia, and the Japanese Pharmacopoeia for measuring particulate matter in injectable drug products.
Response: Change not incorporated. The commenter did not provide data to support the suggested weakness of the method proposed in *FCC*. The commenter also did not provide validation data to support that the USP <788>

Particulate Matter in Injections method is suitable for the measurement of insoluble matter in food-grade amino acid materials.

Monograph/Section(s): L-Arginine, L-Glutamic Acid, L-Glutamine, Glycine, L-Isoleucine, L-Leucine, L-Lysine Monohydrochloride, L-Methionine, L-Valine/ Insoluble Foreign Matter in Amino Acids
Expert Committee(s): Monographs–Food Ingredients
No. of Commenters: 1
Comment Summary #1: The commenter requested tightening the acceptance criteria for total foreign matter in the nine amino acid monograph revisions to a specification that would not allow any particulate matter to be present other than fibers less than 5 mm in length when measured using the USP <788> "*Particulate Matter in Injections*", Method 2: Microscope Particle Count Test. They suggest that the existing method and acceptance criteria would allow amino acid ingredients to pass despite containing small amounts of light foreign matter, such as plastic flakes, that would not be heavy enough to exceed the 5 mg/100g criteria.
Response: Change not incorporated. The commenter did not provide scientific rationale for the requested more stringent acceptance criteria. The commenter also did not provide any supporting data to support the tightened specification.

Monograph/Section(s): Sodium Hyaluronate (From Microbial Fermentation)/ Description
Expert Committee(s): Monographs–Food Ingredients
Expert Committee initiated Change #1: The Expert Committee replaced the words "complex sugar" with "complex carbohydrate" in the *Description* section in order to more accurately describe hyaluronic acid.

Monograph/Section: Sulfur/Inorganic Impurities
Expert Committee(s): Monographs–Food Ingredients
Expert Committee initiated Change #1: The Expert Committee changed the *Acceptance criteria* in the *Inorganic Impurities* test from 0.0001% to 1 mg/kg in order to maintain consistent units in the *FCC*.

Monograph/Section(s): Xylose/Description
Expert Committee(s): Monographs–Food Ingredients
Expert Committee initiated Change #1: The Expert Committee deleted in the Description the sentences, "Xylose is a reducing sugar containing five carbon atoms and including an aldehyde functional group. Like most sugars, it can adopt several structures depending on conditions" to avoid redundancies.

Monograph/Section(s): Zein/Description
Expert Committee(s): Monographs–Food Ingredients
No. of Commenters: 1
Comment Summary #1: The commenter requested that the description include the reported differences between reagent grade and commercial grade zein.

Reagent grade zein is obtained by the alcoholic extraction of dry-milled corn, while most commercial zein is obtained by alcohol extraction of corn gluten meal, the product of corn wet milling. Due to the disrupting effect of sulfur dioxide on disulfide bonds during the wet milling process, the molecular weight and physical properties of commercial zein could differ from those of reagent grade zein.
Response: Comment not incorporated. The Expert Committee will consider the commenter's request through a future revision in order to solicit public comments on this item through the *FCCF*.

Monograph/Section(s): Zinc Acetate/Inorganic impurities, Lead
Expert Committee(s): Monographs–Food Ingredients
Expert Committee-initiated Change #1: The Expert Committee changed the Acceptance criteria in the test for Lead from "NMT 10 mg/kg" to "NMT 2 mg/kg" on the basis that current lead specifications for one of the reagents used to make this ingredient, as well as those for similar ingredients in *FCC*, are lower than the limit originally proposed for this ingredient.

Monograph/Section(s): Zinc Stearate/Lead
Expert Committee(s): Monographs–Food Ingredients
Expert Committee Initiated Change #1: The Expert Committee changed the Acceptance criteria in the test for Lead from "NMT 10 mg/kg" to "NMT 2 mg/kg" on the basis that current lead specifications for one of the reagents used to make this ingredient, as well as those for similar ingredients in *FCC*, are lower than the limit originally proposed for this ingredient.