***COMMENTARY—Food Chemicals Codex (FCC)***
***Seventh Edition, Second Supplement***
**February 28, 2011**

In accordance with USP's Rules and Procedures of the 2010-2015 Council of Experts (Rules), USP publishes all proposed revisions to the *Food Chemicals Codex (FCC)* for public review and comment in the *FCC Forum* (*FCCF).* The *FCCF* is USP's free online journal for providing notice and receiving public comment on *FCC standards*. After public comments are considered and incorporated as the Food Ingredients Expert Committee (FIEC) deems appropriate, the proposal may advance to effective status and be published in *FCC* or, republished on the *FCCF* website for further notice and public comment in accordance with USP's Rules. When a proposed revision advances to effective status and is published in *FCC*, a summary of all comments received and the FIEC's responses are posted in the *Commentary* section of the USP website (www.usp.org).

The *Commentary* section below 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 content 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* section prevails.

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***No comments were received for the following proposals:***

**Solutions and Indicators**
Volumetric Solutions

**Monographs**
Acetoin (Monomer)
Acid Hydrolysates of Proteins
Bergamot Oil, Coldpressed
Ethyl Laurate
Glycerin

***No comments were received for the following proposals (continued):***

**Monographs (continued)**
Hydrochloric Acid
Lycopene Extract from Tomato
Lycopene from Blakeslea Trispora
Magnesium Ammonium Potassium Chloride, Hydrate
Magnesium Phosphate, Monobasic
Maritime Pine Extract
Mineral Oil, High Viscosity
Mineral Oil, Medium and Low Viscosity
Partially Hydrolyzed Proteins
Patent Blue V
Phenethyl Phenylacetate
Phosphoric Acid
Selenomethionine
Succinic Acid
Trehalose
Yeast, Autolyzed
Yeast Extract
(Z)-3-Octen-1-Ol
Zingerone

## COMMENTARY— *FCC* Seventh Edition, Second Supplement

**Monograph/Sections**: Calcium Benzoate/Multiple Sections
**Expert Committee**: Food Ingredients
**Expert Committee Initiated Change #1**: The FIEC changed the first sentence of the *Description* section to be consistent with the description used in the JECFA monograph (63rd JECFA, 2004) for Calcium Benzoate.
**Expert Committee Initiated Change #2**: The FIEC removed the *Acidity or Alkalinity* test procedure and specification because the *Sample solution* cannot be prepared as described due to the limited water solubility of calcium benzoate. The FIEC intends to re-propose this test procedure and specification in the future once a suitable procedure is made available.
**Expert Committee Initiated Change #3**: The FIEC changed the Assay procedure description to clarify the use of the alternative indicator solution to be consistent with that described in the JECFA monograph (63rd JECFA, 2004) for Calcium Benzoate.

**Monograph/Sections**: Appendix XIII – Adulterants and Contaminants in Food Ingredients/Diethylene Glycol and Ethylene Glycol in Glycerin
**Expert Committee**: Food Ingredients
**Expert Committee Initiated Change #1**: The FIEC corrected the last row of the temperature program table to use an initial temperature of 120 degrees instead

of 100 degrees. This change makes the temperature program consistent with the original method cited in the standard.
**Expert Committee Initiated Change #2**: The FIEC added a sentence to the *Figure 1* caption to clarify that peaks in the chromatogram marked with an asterisk originate from the solvent and glycerin.

**Monograph/Sections:** Elemental Impurities by ICP, Appendix IIIC/Multiple
**Expert Committee:** Food Ingredients
**No. of Commenters:** 1
**Comment Summary #1:** The commenter requested that *FCC* not move forward with the proposed methods until guidance is available from the ICH Q3D Expert Working Group, who is working on a harmonized approach for controlling metal impurities.
**Response:** Comment not incorporated. This is not sufficient justification for deferring the proposed methods in this revision. Once guidance is available on harmonized methods for elemental/metals analysis by ICP, the FIEC will review the guidance and harmonize these methods as necessary through future revisions.

**Monograph Section:** Nitrogen determination (Kjehldal method), APPENDIX III NOTE in Method I, Nitrites and Nitrates present
**Expert Committee:** Food Ingredients
**No. of Commenters:** 1
**Comment Summary #1**: Commenter requested that an additional colorimetric indicator used in previous editions of USP-NF be included to the colorimetric indicator suggested for this analysis. Although previous editions of *USP–NF* suggest the use of a colorimetric indicator as an alternative, the titration endpoint is determined potentiometrically, according to the latest *USP-NF* edition (*USP34/NF29*). Moreover, the indicator currently proposed in *FCC* was selected based on a similar compendial method used for a food ingredient, which the FIEC believes is a good alternative for this analysis. The commenter proposed the following indicator:  Bromocresol Green Methyl Red TS (Dissolve 0.15 g of bromocresol green and 0.1 g of methyl red in 180 mL of alcohol, and dilute with water to 200 mL).
**Response:** Comment incorporated.

**Monograph/Sections**: Sodium Iron EDTA/Multiple Sections
**Expert Committee**: Food Ingredients
**No. of Commenters**: 1
**Comment Summary #1**: The commenter requested that the instructions for preparing the *Sample solution* in the test for *UV Absorbance* be changed to:

> "Transfer 1.0 g of the sample to a 100-mL volumetric flask and dilute with water to volume. Transfer 1.00 mL of this solution to a 1-L volumetric flask. Add 20 mL of *Buffer solution* to the flask, and dilute with water to volume."

The change is requested in order to ensure that the pH of the *Sample solution* is consistent. Data supplied by the commenter shows that the pH of the *Sample solution* is more consistent when prepared in the manner suggested by comments.
**Response:** Comment incorporated.
**Comment Summary #2:** The commenter requested that the following statement be added to the *Analysis* under the test for *Sulfate (As Barium Sulfate)*: "Alternately a turbidimeter may be used." This change is requested to clarify that users are not required to visually determine the endpoint of the test.
**Response:** Comment incorporated.