General Chapters <232> Elemental Impurities—Limits and <2232> Elemental Contaminants in Dietary Supplements Applicable as of January 1, 2018

Type of Posting: General Announcement

Posting Date: 17-Nov-2017

Expert Committee: Council of Experts, General Chapters—Chemical Analysis

General Notices Section 5.60.30 Elemental Impurities in USP Drug Products and Dietary Supplements, as it appears in the currently official Supplement 2 to *USP 40–NF 35*, makes General Chapters <232> Elemental Impurities–Limits and <2232> Elemental Contaminants in Dietary Supplements applicable to drug product and dietary supplement monographs, respectively, on January 1, 2018. This revision to General Notices specifying the January 1, 2018 effective date was made by the Council of Experts and published via Revision Bulletin on March 27, 2015 to more closely align the implementation date of USP's elemental impurities standards with the ICH Q3D Guideline for Elemental Impurities.

Also as of January 1, 2018, the omission of General Chapter <231> Heavy Metals and all references to it will be official, and as such, General Chapter <231> will not be considered by USP to be available for demonstration of conformance with USP–NF requirements. Please be aware that in USP 41–NF 36, which is currently published and will become official on May 1, 2018, General Chapter <231> still appears in full, with the following note, "Chapter to remain official until January 1, 2018. After January 1, 2018, this chapter will no longer be required. See General Notices 5.60.30.)." References to General Chapter <231> also will remain in this version with revision markup that notes their omission date of January 1, 2018. General Chapter <231> and its references will be removed from the USP–NF as of USP 42–NF 37.

Should you have any questions or comments, please contact Kahkashan Zaidi, Ph.D., Principal Scientific Liaison (301-816-8269 or kxz@usp.org).