<u>Withdrawal of Notice of Intent to Revise for Reinstatement of References to General Chapter <231> Heavy</u> <u>Metals in Monographs and General Chapters Published in the Second Supplement to USP 38–NF 33</u>

Type of Posting: Notice of Intent to Revise (withdrawal)

Posting Date: 26–Jun–2015

Targeted Official Date: Not applicable

Archive Date: 24–Jun–2016

In a notice of intent to revise posted on June 1, 2015, USP announced that it intended to reinstate by Errata several references to General Chapter <231> Heavy Metals. A list of the monographs and general chapters that USP intended to revise was included in that Notice. The purpose of this Notice is to rescind that intention.

The intended Errata were considered to be necessary in cases where references to General Chapter <231> were replaced with references to General Chapter <561> Articles of Botanical Origin. The purpose of the Errata was to reinstate these references to <231> following the revision to General Notices 5.60.30 Elemental Impurities in USP Drug Products and Dietary Supplements, which specified January 1, 2018 as the date when General Chapters <232> Elemental Impurities–Limits and <2232> Elemental Contaminants in Dietary Supplements would become broadly applicable to drug products and dietary supplements. After further review of these intended Errata, USP has determined that reinstatement of the references to <231> is not necessary because the application of the new elemental impurity standards through references to <561> is not related to the application of such standards through General Notices 5.60.30. As noted in the FAQs posted on USP's website, <232> and <2232> are already official and can be made applicable through reference in a monograph or in an applicable general chapter, independent of their broader application through General Notices 5.60.30. Thus, the original revisions to include references to <561> will become official on December 1, 2015 with Second Supplement to *USP 38–NF 33* as originally intended.

A link to the previous Notice of Intent to Revise, including the list of monographs and general chapters that was originally cited, can be found here.

Should you have any questions or comments, please contact Mario Sindaco, Director of Compendial Affairs and Executive Secretariat, Council of Experts (301-816-8246 or mys@usp.org).