General Chapter <561> Articles of Botanical Origin

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Expert Committee: General Chapters—Chemical Analysis

Reason for Revision: Compliance

In accordance with the Rules and Procedures of the 2010-2015 Council of Experts, the General Chapters—Chemical Analysis Expert Committee has revised General Chapter <561> Articles of Botanical Origin.

A request for revision with supporting data was received to revise the limit of bromide under the section Pesticides of the chapter, because some lots of articles from botanical origin listed in this pharmacopeia fail the current requirements even when grown in organic conditions since bromide is naturally present in plants. The Expert Committee has recognized that the natural occurrence of bromide in some pharmacopeial articles of botanical origin may exceed the currently official limit (50µg/g). However, the Expert Committee is convinced that removal of the limit for bromide is not a rational approach due to the concern with the toxicity arising from unknown methylated compounds derived from the practice of fumigation with methyl bromide as a pesticide.

As a result, the Expert Committee has decided to revise the limit for bromide from 50µg/g to 125 µg/g to address its possible origination from the use of methyl bromide as a fumigant. The proposed limit is harmonized with Environmental Protection Agency (EPA) requirements set in 40CFR180.123(a)(2)(i)(D) for processed foods not otherwise listed under 40CFR180.123(a)(2)(i) and under 40CFR180.521(a)(3), which would include some of the herbal drugs listed in this pharmacopeia.

The General Chapter <561> Articles of Botanical Origin Revision Bulletin supersedes the currently official monograph. This Revision Bulletin will be incorporated in First Supplement to USP 38–NF 33.

Should you have any questions, please contact Maria Monagas, Scientific Liaison to the General Chapters—Chemical Analysis Expert Committee at (301-230-3244 or coo@usp.org).

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