AMERICAN HERBAL PRODUCTS ASSOCIATION

July 31, 2015

United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790
Attn: Anton Bzhelyansky
via email: anb@usp.org

Re: Proposed USP General Chapter <2251> (Correspondence number C144928)

Dear Mr. Bzhelyansky:

The United States Pharmacopeia published in PF 41(3) an In-Process Revision in the form of new proposed USP General Chapter <2251> (hereinafter Proposed USP <2251>), titled in the proposal as "Adulteration of dietary supplements with drugs and drug analogs."

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and international companies doing business as growers, collectors, processors, manufacturers and marketers of herbs and herbal products. Some AHPA members are engaged in the commerce of herbs and herbal products in the dietary supplement category and therefore have an interest in the subject of Proposed USP <2251>.

These comments are therefore submitted on behalf of AHPA's members and consist of recommendations to consider in developing Proposed USP < 2251>. Note that these comments are limited in scope such that the absence of comments here to any provision of Proposed USP <2251> represents neither explicit nor implicit agreement nor disagreement with any provision not addressed herein.

The described products are not dietary supplements

AHPA has significant concerns that the title for Proposed USP <2251>, some of the text within the proposed chapter, and the intended placement of the proposed chapter within USP's Dietary Supplement Chapters imply that products that contain undeclared drugs or drug analogs are dietary supplements. They are not. Any such product is, in fact, a misbranded drug.

For example, when the U.S. Department of Justice (DOJ) filed an indictment in April 2015 against a seller of products that were found to contain undeclared sibutramine, analogs of sibutramine, and phenolphthaleinin, the felony charge brought by DOJ was that the defendant "did unlawfully introduce and deliver for introduction into interstate commerce, and caused the introduction and delivery for introduction into interstate commerce, misbranded drugs" (emphasis added). The only mention of the term "dietary

supplements" in the indictment was to allege the defendants had "introduced into interstate commerce purportedly all-natural dietary supplements that were sold as weight loss products" (emphasis added).[1]

In addition, the U.S. Food and Drug Administration (FDA) has made it clear that such products are not dietary supplements. A consumer advisory first issued by FDA in March 2011 cites Michael Levy, director of FDA's Division of New Drugs and Labeling Compliance, as stating: "These products are masquerading as dietary supplements—they may look like dietary supplements but they are not legal dietary supplements."[2]

Of additional relevance is that some of the misbranded drug products that FDA has found to contain undeclared drugs and drug analogs are not falsely represented as dietary supplements but are instead falsely represented as conventional foods. For example, on November 4, 2014 FDA issued a public notification to advise consumers not to purchase V26 Slimming Coffee, a misbranded drug product promoted for weight loss and found to contain undeclared sibutramine.[3] This product was falsely represented as a conventional food to be consumed as a hot beverage and apparently bore no labeling to suggest it was marketed as a dietary supplement. Similarly, in an August 2010 Warning Letter addressed to the marketer of Magic Power Coffee FDA noted that even though this product was identified by the marketer as a dietary supplement it failed to meet the requisite statutory definition due to its representation as a conventional food. FDA also clearly stated in this letter that the product was not a food ("…if 'Magic Power Coffee' were a food, which it is not…") but was in fact a drug ("…'Magic Power Coffee' is an unapproved new drug … and a misbranded drug…").[4]

AHPA therefore requests that USP revise all language in Proposed USP <2251> to remove any confusion as to the legal status under the Food, Drug & Cosmetic Act (FDCA) of any product that contains an undeclared drug or drug analog.

AHPA's requests for revisions to Proposed USP <2251>

More specifically, AHPA requests the title of Proposed USP <2251> be changed to refrain from identifying the subject products as "dietary supplements" (since they are not dietary supplements) and AHPA presents here optional suggested revisions to the title:

[1] U.S. District Court for the Middle District of Pennsylvania; United States of America versus Cheryl Floyd AKA Cheryl Floyd Brown; Criminal Case No. 1:15-CR-00058-SHR; Document 1. AHPA can provide this document upon request.

[2] http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm246744.htm. Accessed July 30, 2015.

[3] http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm421802.htm. Accessed July 30, 2015.

[4] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm225432.htm. Accessed July 30, 2015.

- "Adulteration of products falsely identified as 'dietary supplements' or conventional foods with undeclared misbranded drugs and drug analogs"
- "Methods for detection of undeclared misbranded drugs and drug analogs in products falsely identified as 'dietary supplements' or conventional foods"
- "Methods for detection of undeclared misbranded drugs and drug analogs in orally-consumed products"

AHPA also requests significant revisions to the text of Proposed USP <2251> consisting of at least the following:

- In the introductory briefing paragraph, removal of the struck-through text and addition of the bolded text as presented below:

  "This new general chapter provides tools for detection of **misbranded drugs falsely labeled as** dietary supplement**s or occasionally as a conventional foods and** ~~adulteration~~ **adulterated** with extraneously added **and undeclared** synthetic compounds. The illegal addition of synthetic substances to products **falsely** marketed as dietary supplements **or foods** constitutes a significant threat to consumer health, considering that these ~~products, administered without medical supervision,~~ **undeclared ingredients** may contain toxic constituents or substances whose safety has never been examined, and whose interaction with medications may be unpredictable or lethal. The proposed chapter suggests multiple methods for detection of adulteration. It is advisable to use several screening techniques to maximize the potential for adulteration detection, because no single methodology is universally applicable. Presently, the chapter targets ~~supplements~~ **products** adulterated with phosphodiesterase type 5 inhibitors; subsequent revisions will include methodologies specific to analysis of adulterated weight loss and sports performance enhancement products. It is anticipated that this chapter will be updated regularly."

- In the first sentence of the Introduction, removal of the struck-through text and addition of the bolded text as presented below:

  "The illegal addition of undeclared synthetic compounds to products **falsely** marketed as dietary supplements ~~(DS)~~ **and occasionally as conventional foods** is a serious problem."

- A change to the title of the section currently called "Dietary supplement adulteration category" to "Misbranded drug adulteration categories" or such similar title that avoids erroneously describing these misbranded drugs as dietary supplements.

- A change to the title of the section currently called “Dietary supplement bulk powders and dosage forms” to “Adulterated bulk powders and dosage forms” or such similar title that avoids erroneously describing these misbranded drugs as dietary supplements.
- Throughout the document, replacement of the term “supplements” or “dietary supplements” and the abbreviation “DS” with the word “products” or the phrase “products falsely labeled as dietary supplements or occasionally as conventional foods” or such similar phrase that avoids erroneously describing these misbranded drugs as dietary supplements.
- Any additional changes that are needed to ensure that no person could possibly mistake, by reading Proposed USP <2251>, that these unlawful misbranded drugs are dietary supplements, since they are not dietary supplements, or that implies that USP erroneously believes these products to be dietary supplements or to meet the definition of dietary supplements under the FDCA.

Finally, AHPA notes that Proposed USP <2251> is proposed to be added as a Dietary Supplement Chapter within USP. AHPA strongly objects to such classification and requests that the chapter be located elsewhere in USP for the reasons already discussed elsewhere in these comments.

USP’s commitment to accurate nomenclature; request for meeting

USP has long recognized the importance of precision in the titles of its monographs, as is demonstrated by USP General Chapter <1121> on Nomenclature. This value on nomenclatural precision and accuracy must be applied through all of USP’s monographs, and is necessary in Proposed USP <2251> in order to avoid any confusion as to the regulatory status of the unlawful misbranded drugs that are the subject of the proposed monograph.

AHPA appreciates the opportunity to comment on proposed USP General Chapter <2251>. In closing, AHPA requests on opportunity to meet with appropriate USP staff to further discuss the issues raised herein.

Respectfully submitted,

Michael McGuffin

President, American Herbal Products Association
(301) 588-1171 x201; mmcguffin@ahpa.org

cc: Gabriel Giancaspro (gig@usp.org)
Maged Sharaf (msharaf@ahpa.org)