International Pharmaceutical Excipients Council of the Americas

Janeen Skutnik-Wilkinson
Chair

March 1, 2021

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RE: IPEC-Americas endorsement of IFAC's comments on proposed new General Chapter <2740> and <2800> and proposed revision to General Chapter <2750>

Dear Dr. Yoo and Dr. Davydova,

IPEC-Americas represents more than 50 excipient manufacturers, distributors and pharmaceutical/biopharma companies to support the safe production and use of excipients. This letter represents the IPEC-Americas membership. A complete list of IPEC-Americas member companies can be found at: https://ipecamericas.org/what-ipec-americas/member-companies. IPEC-Americas is dedicated to working closely with regulatory authorities, industry organizations and scientific bodies (globally) to advance public health on matters relating to the quality, safety, manufacture, distribution, use and functionality of excipients. IPEC is the sole association representing excipients.

Members of the International Pharmaceutical Excipients Council of the Americas (IPEC-Americas) have reviewed IFAC's Comments on Proposed New General Chapters <2740> and <2800> and Proposed Revisions to General Chapter <2750> that were sent to your attention on July 31, 2020 and with this response would like to endorse their comments, which are attached.

Respectfully yours,

Janeen Skutnik-Wilkinson
Chair, IPEC-Americas

International Food Additives Council

Submitted via Email

July 31, 2020

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RE: IFAC Comments on Proposed New General Chapters <2740> and <2800> and Proposed Revisions to General Chapter <2750>

Dear Dr. Yoo and Dr. Davydova,

The International Food Additives Council (IFAC) is a global association representing manufacturers and end-users of high-quality materials used in a variety of products, including foods, dietary supplements, pharmaceuticals, and other applications. IFAC is commenting on the U.S. Pharmacopeia's (USP) proposed new General Chapters <2740> and <2800>, as well as proposed revisions to General Chapter <2750>, in follow-up from the May 2020 USP Dietary Supplements Stakeholder Forum.

General Chapter <2740> *Manufacturing Practices for Dietary Ingredients*
The newly proposed General Chapter <2740> is intended to be separate from the existing General Chapter <2750> *Manufacturing Practices for Dietary Supplements* and would apply only to dietary ingredients. IFAC does not understand USP's intent in proposing this new General Chapter and believes is duplicative and potentially conflicts with existing U.S. regulations related to the production of ingredients used in dietary supplements.

The U.S. Food and Drug Administration's (FDA) expectations around manufacturing practices for dietary ingredients are clearly outlined in the Code of Federal Regulations (CFR) and the FDA Food Safety Modernization Act (FSMA) implementing rules. IFAC does not see a reason for USP to duplicate this information or add or change expectations for dietary ingredient manufacturers. The creation of additional recommended manufacturing practices outside what is already required by FDA, as part of the promulgation of regulations and public rule making, would add undue burden on industry and could create confusion among dietary ingredient producers, dietary supplement manufacturers, and ultimately consumers. In addition, with the way that the Chapter is drafted, it leaves too much open to interpretation, especially when additional requirements are put in place by USP when they are not required by the U.S. FDA in 21 CFR Parts 111 or 117. Therefore, IFAC does not support creation of General Chapter <2740>.

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General Chapter <2750> *Manufacturing Practices for Dietary Supplements*
IFAC does not support the proposed revisions to General Chapter <2750>. This Chapter is a blend of various requirements from 21 CFR Part 111 with additional interpretation and inclusion of pharmaceutical requirements. Some additions involve validation of manufacturing steps, which is not a requirement set out by the FDA for foods and dietary supplements. IFAC strongly disapproves of USP creating their own guidelines that go above and beyond FDA requirements.

The FDA and other national regulatory authorities determine the standards and regulations that manufacturers of dietary supplements and ingredients should meet. Since the USP is considered an official compendium in the U.S. and many other countries, it is not appropriate for the USP to write additional guidelines that supersede regulatory authorities. This leads to conflicting expectations and confusion within the industry. If USP continues ahead with finalizing General Chapter <2750> as it is currently revised, where companies are asked to conform to additional and unnecessary stipulations outside of what is legally required by regulatory authorities, companies may consider abandoning USP as a standard setting organization given the substantial increased costs that will arise from implementing this guideline. Other organizations exist which review and certify facilities and products based on standards grounded in the dietary supplement regulations as adopted by national authorities and other industry accepted third party standards. This decision to advance the USP standards over and beyond what is legally required and reasonably possible to achieve by manufacturers will reduce USP's visibility with the U.S. consumer and weaken USP's position.

General Chapter <2800> *Multi-Ingredient Dietary Supplement Products—Development of Quality Tests*
IFAC does not support creation of this new General Chapter. General Chapter <2800> would be applicable to the products for which there are existing dosage forms or ingredient monographs for the ingredients found in a multi-ingredient product. Dietary ingredients typically have their own monographs that contain appropriate quality information, so there is no need to create an additional monograph for dietary supplements that contain multiple ingredients; this Chapter would be duplicative. There are far too many "multi-ingredient" supplements manufactured and it is unclear how USP would determine what "appropriate tests methods" should be applied to those. IFAC would like clarification from USP on how this Chapter would increase or help ensure quality or consumer safety, provided the ingredients are already covered by existing monographs and quality specifications, in addition to the finished product having its own set of release criteria. The FDA regulates new dietary ingredients, so it is unclear what USP would contribute to this process by adding this General Chapter.

Thank you for the opportunity to provide comment. Please let me know if you have any questions.

Sincerely,

Robert Rankin

Robert Rankin
Executive Director

CC: Dr. Gabriel Giancaspro, Vice President-Science, Dietary Supplements & Herbal Medicines, USP

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