

Katherine Ulman

From: Natalia Davydova <ND@usp.org>
Sent: Tuesday, March 2, 2021 3:41 PM
To: IPEC Americas; Seong Jae Yoo; Kit S. Goldman; Binu Koshy
Cc: Douglas G Muse (muse_douglas_g@lilly.com); 'Janeen SkutnikWilkinson' (janeen.skutnikwilkinson@biogen.com); Jennifer Putnam
Subject: RE: IPEC-Americas endorsement of IFAC's comments on proposed new General Chapter <2740> and <2800> and proposed revision to General Chapter <2750>
Attachments: IPEC-Americas endorsement of IFACs comments on GCs 2740_2800_2750.pdf
Follow Up Flag: Follow up
Flag Status: Flagged

Dear Kimberly,

Thank you for your communication. Please consider this email as confirmation that your message is receiving our attention. The IPEC-Americas, in a letter dated March 1, 2021, expressed support for IFAC's comments on the proposed new general chapters <2740> and <2800> and the proposed revisions to general chapter <2750> that were sent to us in July 31, 2020. Therefore please allow me to provide some clarifications to the situation with the IFAC comments:

1. Regarding general chapter <2750> Manufacturing Practices for Dietary Supplements: the general chapter revision was published in PF 46(2) [Mar. – Apr. 2020] with extended comments deadline on July 31, 2020. We received comments from several commenters (including IFAC) during the commentary period. Expert Committee discussed all the comments received. The chapter was finalized based on the recommendations from the Expert Committee. The finalized version of the chapter was balloted and approved to be official on August 1, 2021. A summary of comments received and the appropriate Expert Committee's responses are available online: https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/usp-nf-commentary/usp-nf-2021-issue-2-commentary.pdf
2. Regarding general chapter <2740> Manufacturing Practices for Dietary Ingredients: the general chapter proposal was published in PF 46(6) [Nov. 2020– Jan. 2021] with comments deadline on January 31, 2021. Dr. Binu Koshy, a scientific liaison for the chapter, is aware of the IFAC letter sent on July 31, 2020. I am including him in this email, so that he also be aware of your message. I believe he will discuss IPEC and IFAC comments with the EC members.
3. Regarding general chapter <2800> Multi-ingredient Dietary Supplement Products – Development of Quality Tests: the chapter is currently under development. The purpose of this chapter is to establish guidelines for development of quality tests for multi-ingredient dietary supplement finished products when individual monographs for those ingredients or their finished products exist. The chapter is not available for comments yet. We plan to organize an Open Forum on General Chapter <2800> to share the idea of the chapter and to receive feedback from stakeholders on the proposed general chapter content before PF submission.

Once again we thank you for your communication.

With kind regards,
Natalia



Natalia Davydova, Ph.D.

Senior Scientific Liaison
Dietary Supplements
U.S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852
Email: nd@usp.org
Tel: (301) - 816-8328
Fax: (301) - 816-8157

This response has been provided for informational purposes only, and should not be construed as an official interpretation of USP text, or be relied on to demonstrate compliance with USP standards or requirements.

From: IPEC Americas <ipecamer@ipecameras.org>

Sent: Monday, March 1, 2021 4:52 PM

To: Seong Jae Yoo <SJY@USP.org>; Natalia Davydova <ND@usp.org>

Cc: Douglas G Muse (muse_douglas_g@lilly.com) <muse_douglas_g@lilly.com>; 'Janeen SkutnikWilkinson' (janeen.skutnikwilkinson@biogen.com)' <janeen.skutnikwilkinson@biogen.com>; Jennifer Putnam <jennifer.putnam@perrigo.com>

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

****CAUTION! This email originated from outside of USP. Do not open attachments or click links if you do not recognize the sender.****

Attached are IPEC-Americas comments related to the above referenced subjects.

Please confirm receipt of this message.

Many thanks,

Kim

Kimberly R. Beals
Executive Director
IPEC-Americas
3138 10th St. N. Suite 500
Arlington, VA 22201
571-814-3451 (office)
571-239-4531 (cell)