



International Pharmaceutical Excipients Council of the Americas

*Janeen Skutnik-Wilkinson
Chair*

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Jacqueline Starks
Assistant Scientific Liaison
United States Pharmacopeial Convention
12601 Twinbrook Parkway
Rockville, MD 20852
e-mail: jws@usp.org

Cc: Catherine Sheehan
Hong Wang
John Giannone

Re: USP Excipients Open Forum, February 11th and 12th, 2021

Dear Ms. Starks,

Members of the International Pharmaceutical Excipients Council of the Americas (IPEC-Americas) are interested in continued dialog and collaboration in the development of meaningful public standards that ensure patients' safety and access to quality medicines. This communication is a follow up on the February USP Excipients Open Forum.

IPEC-Americas Background

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.

IPEC-Americas Follow-Up Request

Several IPEC-Americas member companies participated in the February Excipients Open Forum. Many comments and questions were submitted via the chat during the forum. With limited time for Question and Answer (Q and A) sessions, USP was not able to respond to each question/comment during the forum and committed to providing written responses and also to sharing the presentation slides with all attendees. To date, neither have been posted on-line or otherwise shared with IPEC-Americas.

When will USP issue the written responses to the complete list of comments and questions submitted by stakeholders and publish the USP presentation slides?

Transparency is a critical component of the USP-Stakeholders working partnership. IPEC-America's recommends that future Open Forums allow more time for discussion/Q&A for each topic to ensure stakeholders have the opportunity for open dialogue with USP.

While the virtual format has been a necessity for organizations since the beginning of the Covid-19 pandemic, it does not allow participants to view the list of attendees or hear the questions/comments submitted by other attendees.

Will USP release a list of the attendees from the February Excipient Open Forum? If so, when will it be available and how will it be shared? If not, can USP clarify why?

IPEC-Americas recognizes the efforts of USP to reach out to stakeholders in an interactive and engaging manner. The Excipient Open Forum was one step in the USP-Stakeholder working partnership. Continued open dialog with all stakeholders, including the FDA, will facilitate the development of meaningful global standards. USP indicated during the February Excipient Open forum that additional opportunities for interactive engagement, including Stakeholder Forums and Open Forums, are being planned to discuss the ongoing issues concerning excipients.

What additional Stakeholder Forum, Open Forums, or other interactive stakeholder events are scheduled for 2021? Will stakeholders be involved in planning and/or presenting at future events?

If none have been scheduled, what is the most effective way for stakeholders to have interactive communications with USP?

Further, IPEC-Americas recognizes that USP intends to create a collaborative working group (USP, FDA, and industry representatives) for the continued development of composition type tests in excipient monographs.

When will this working group be established and how will the members be chosen?

IPEC-Americas values the opportunity to partner with the USP, other Stakeholders, and the FDA for collaboration on the development of global standards which ensure the quality and safety of excipients.

Respectfully yours,



Janeen Skutnik-Wilkinson
Chair, IPEC-Americas