International Pharmaceutical Aerosol Consortium on Regulation and Science

1500 K Street NW • Washington DC • 20005
Telephone +1 202 230 5607 • Fax +1 202 842 8465
Email info@ipacrs.org • Web www.ipacrs.org

July 31, 2017

IPAC-RS Comments on USP Stim. Article "Proposals for Data Interpretation in the Context of Determination of Aerodynamic Particle Size Distribution Profile for Orally Inhaled Products." [Pharm.Forum 43(3) 2017]

The International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS[1]) welcomes the "Stimuli to the revision process" article entitled "Proposals for Data Interpretation in the Context of Determination of Aerodynamic Particle Size Distribution Profile for Orally Inhaled Products".

IPAC-RS supports the article's goal of raising public awareness of the various ways that an aerodynamic particle size distribution could be characterized.

Some specific comments are provided on the following page.

If you would like to discuss further, please do not hesitate to contact us.

Sincerely,

Svetlana Lyapustina,
IPAC-RS Secretariat.

[1] IPAC-RS seeks to support the regulatory science of orally inhaled and nasal drug products (OINDPs) by collecting and analyzing data, conducting joint research projects, and engaging with the wider regulatory and scientific community on topics of importance to the stakeholders interested in the development and availability of high quality, safe and efficacious OINDPs. See IPAC-RS Homepage at http://ipacrs.org/.

Specific Comments

Location	Original Language	Proposed Changed Language	Justification	Importance
Background and Scope		*Add* "A Cascade Impactor is not a lung simulator, but an in-vitro piece of equipment that can detect APSD changes or trends in support of Quality Control testing or Stability testing."	There are unfortunately still too many publications and presentations that view CI data as representation of lung deposition, which is incorrect and misleading. A USP chapter is a unique opportunity to reinforce the distinction between in-vitro and in-vivo deposition, and underscore proper use of CI data.	Critical
Pg. 1, Background, ¶2, sentence 3.	"Nonsizing components" of the CI apparatus include the induction port (inlet); the preseparator (if used); and the first stage [except for the next-generation impactor (NGI)].	"Nonsizing components" of the CI apparatus include the induction port (inlet); the preseparator (if used); and the first stage [except when the next-generation impactor (NGI) is employed].	Clarity	Minor
Pg. 6, Sub-Fractions	*Suggested text to be added at end of paragraph or perhaps a second paragraph in this section.*	As an alternate approach, if the data have been fitted to a sigmoid curve as suggested in Proposal 3, knowledge of the fitting model should enable calculation of %FPM smaller than a particular cut-point size of interest.	Additional approach for calculation of "%FPM smaller than …".	Regular