IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

1500 K Street NW • Washington DC • 20005
Telephone +1 202 2305607 • Fax +1 202 842 8465
Email info@ipacrs.org • Web www.ipacrs.org

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TO: FDA via public docket at https://www.regulations.gov/docket/FDA-2021-D-0166

RE: Draft guidance for industry "ICH Q12: Implementation Considerations for FDA-Regulated Products | FDA"

The International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) appreciates the Agency's issuance of a draft guidance "ICH Q12: Implementation Considerations for FDA-Regulated Products | FDA". IPAC-RS would like to offer the following supporting comments.

IPAC-RS is an association of companies that develop, manufacture and market orally inhaled and intranasal drug products, with a mission to advance regulatory science for these product types.

Over the years, IPAC-RS working groups have developed and publicized recommendations for improved approaches to characterization and control of drug-device combination products.

For example, the IPAC-RS Cascade Impaction Working Group has developed Abbreviated Impactor Measurements (AIM) and Efficient Data Analysis (EDA) as innovative alternative methods for control of aerodynamic particle size distributions. ICH Q12 provides a systematic framework for implementing the AIM and EDA in product development and regulatory submissions for products intended for respiratory delivery.

Similarly, Established Conditions, which is a key concept of ICH Q12, has been a topic of ongoing discussion within IPAC-RS, especially as applied to the device constituent parts of a drug-device combination product.

IPAC-RS would welcome further public discussion of ICH Q12 implementation, in particular for complex dosage forms such as orally inhaled and intranasal drug products. IPAC-RS would be happy to engage in these future discussions.

ABOUT IPAC-RS

IPAC-RS is a non-profit association of companies that develop, manufacture, or market orally inhaled and nasal drug products (OINDPs) – both brand-name and generic. Through its industry members, as well as through collaborations with academia, pharmacopeias, standard-setting bodies, patient and healthcare provider representatives, pertinent trade associations, and other stakeholders, IPAC-RS explores, researches and advances regulatory-science issues important to OINDP development, regulation, production, and control. IPAC-RS has demonstrated its commitment to productive collaborations during its long history of engaging the broader scientific and regulatory community to promote deeper understanding and build consensus on key topics impacting these products.