IPAC-RS
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TO: FDA via public docket at https://www.regulations.gov/docket?D=FDA-2019-D-5573

Re: Draft guidance for industry "Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a BLA, NDA or ANDA"[1] (Docket No. FDA-2019-D-5573)

The International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) commends the Agency for publishing a draft guidance for emergency-use injectors. As an association of companies that develop, manufacture and market orally inhaled and nasal drug products (OINDPs), IPAC-RS is concerned about the potential inappropriate application of approaches proposed in this guidance to OINDPs, in relation to the topics raised in lines 52 to 58 of the draft guidance.

The guidance should indicate that these recommendations may be appropriate where the 'Indications and Usage' section of a product calls for use in emergency treatment and if the section does not utilize this use case and words, then the guidance is not applicable. For example, the naloxone hydrochloride nasal spray is intended for immediate administration as emergency therapy in settings where opioids may be present and therefore aspects of this guidance may be considered applicable.

It is critically important, therefore, for FDA to come to a reasonable and unambiguous definition of the term "***emergency-use***". This is particularly important because the testing that FDA describes in this guidance is rigorous and challenging and likely would not be appropriate for most products. Without a narrow, clear definition of "emergency-use," FDA may end up imposing overly-broad and burdensome requirements for classes of products for which rigorous failure testing is unnecessary for ensuring patient safety.

IPAC-RS would appreciate it if the Agency made the distinction clear, e.g., through an additional sentence about scope boundaries in the Introduction or in a footnote.

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.

[1] FDA CDER. Draft guidance for industry "Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a BLA, NDA or ANDA" (April 2020) at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-demonstrating-reliability-emergency-use-injectors-submitted-under-bla-nda