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Ms. Leslie Kux
Assistant Commissioner for Policy
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2015-D-3438 for "Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use.

Dear Ms. Kux:

The Association for Professionals in Infection Control and Epidemiology (APIC) appreciates the opportunity to provide comment to the Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) on *Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-dose, Single-Dose and Single-Patient Use Containers for Human Use, Guidance for Industry.* APIC is a non-profit, multidisciplinary organization representing over 15,000 infection preventionists, whose mission is to create a safer world through prevention of infection. APIC has been a strong advocate for safe injection and infusion practices with our members, healthcare providers and consumers through support and involvement with various national programs and projects, education, competency, and advocacy.

APIC is encouraged that the FDA is strengthening their industry guidance related to labeling of injectable materials, as improper management and misuse of injectable medications and biologicals has resulted in microbial contamination and been implicated in the transmission of bloodborne illnesses between patients. APIC shares the FDA's concern about these inappropriate practices, as these outbreaks cause immeasurable harm to patients and result in significant cost in outbreak investigations, patient testing, treatment and litigation. We recognize the focused guidance of this document is for the purpose of providing recommendations on the selection of appropriate package type terms and selection of appropriate discard statements.

APIC applauds FDA's effort to provide relevant and understandable terminology for injectable medical products in an effort to prevent future misuse of these products by healthcare personnel. We strongly agree with the newly enhanced definitions for Multiple-Dose and Single-Dose Containers. The addition of the new term Single-Patient-Use, in addition to the sunsetting of the term Single-Use, provides

further clarity for healthcare personnel as to the proper use of such containers. Moreover, the diagram illustrating how to determine the appropriate package type term is very clear and we envision this as a very usable tool for educating users of these products on the proper utilization of the different types of containers for patient care.

Terminology and labeling are key important steps in the effort to assist with compliance related to the intended use of these items. APIC applauds FDA for these efforts and recommends FDA consider providing additional requirements in the near future for industry on Single-Dose containers such that reentry or reuse of such containers is prohibited by product design features. As rightly noted in previous guidance provided by the FDA related to excess volumes,[1] there are instances where a single-dose container may contain more drug than is required by a single dose, but is not intended for use following removal of a single dose. Development of an added design feature to prohibit container re-entry would drastically reduce the ability to reuse any remaining product in the container on a patient or patients. This would also further avoid reusing a product in situations where the terminology is not noted on a container. Currently, if terminology is not present on the container due to size, it is the user who must then determine what type of container it is intended to be. This lack of clarity could result in reuse of such unlabeled containers when the outer packaging is not readily available and would continue to be a risk for spread of bacterial and/or viral pathogens for patients.

We appreciate the FDA's direction to improve patient safety with the recommendations in this guidance document and encourage continued targeted attention to this issue as future guidance for industry is developed. Ongoing safety concerns remain in relation to excess drug volumes when using weight-based dosing, and drug shortage situations. The shortage issue is particularly vexing as it financially disincentivizes the production and purchase of small vials by the manufacturer and users, respectively. Thus, the shortage issue overrides the safety issue. On this last point, FDA should consider whether its regulatory approval process imposes any unnecessary impediments. For example, we have been advised that generic injectable drug manufacturers may not propose smaller volume packaging than what was approved under the original manufacturer's FDA application, without undergoing additional, potentially lengthy and cost-prohibitive reviews.

Thank you for the opportunity to review this draft guidance document and provide input on behalf of our members. We look forward to working with the FDA to continue to promote patient safety through improved manufacturing practices.

Sincerely,

Mary Lou Manning, PhD, CRNP, CIC, FAAN, FNAP
2015 APIC President

[1] FDA Guidance for Industry on *Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products.*