



December 21, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Re: FDA-2015-D-3438: 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Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use; Draft Guidance for Industry

To Whom It May Concern:

The American Association of Nurse Anesthetists (AANA) is the professional association for more than 49,000 Certified Registered Nurse Anesthetists and Student Registered Nurse Anesthetists, representing over 90 percent of the nurse anesthetists in the United States (US). AANA welcomes the opportunity to submit comments regarding the US Food and Drug Administration (FDA) draft guidance for industry titled “Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose,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.”

Commitment to Patient Safety and Safe Injection Practices

The AANA actively supports evidence-based injection practices for the safety of all patients. As a founding member of the Safe Injection Practice Coalition (SIPC) and the One & Only Campaign, the AANA collaborates with the Centers for Disease Control and Prevention (CDC), FDA and other coalition partners to promote safe injection practices within the healthcare industry. Concerning drug shortages and their implications for safe injection practices, the AANA has provided survey data and recommendations to the FDA, and participated in panel discussions with the FDA, aimed at seeking solutions to this important patient safety issue. The AANA has also developed extensive infection control and safe injection practice evidence-based guidelines, which include the “[Safe Injection Guidelines for Needle and Syringe Use](#)” and the “[Infection Prevention and Control Guidelines for Anesthesia Care](#).” In addition, the AANA has created resources for members analyzing the application of US Pharmacopeial Convention (USP) <797> standards to anesthesia practice.

Harmonization and Collaboration among Key Stakeholders

The AANA applauds the FDA for developing guidance with detail and consistency for definitions of various medication package types. The addition of clear identification of a “single-patient-use container,” which is intended to be used multiple times for a single patient, is an important new differentiation for prevention of infection. The AANA recommends that the FDA collaborate with the USP to standardize and harmonize medication package terms, definitions and other information. Consistent and standardized medication labeling reduces variability in the appearance and labeling of an injectable medical product to prevent errors that may harm patients.

Additionally, the AANA recommends that FDA consult with organizations such as the SIPC, an interprofessional collaborative that includes CDC, FDA, industry, and professional organizations, to assess how the proposed guidance may impact patient care provided across all settings.

American Association of Nurse Anesthetists

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Container Labeling

Certain vials and ampules have very limited surface area for labeling and package inserts for stock medications may not be readily available to clinicians. The AANA believes that a standardized web resource for medication labeling terms, definitions, and discard dates, as well as medication management, safe injection practices and infection prevention, would be extremely valuable to clinicians. A resource summary table and an app would provide clinical reference for compliance with the guidelines.

As the guidance recommends that the necessary labeling changes be adopted within two years of the publication of the final guidance, there will be a transitional period where “old” and “new” versions of medication labels are potentially used simultaneously in the same clinical setting, which may contribute increased risk of improper preparation and use of the medication. In the interim, there is continued opportunity to communicate best injectable medication practice.

Coordinated Education for Engagement

Healthcare professional organizations and patient safety coalitions, such as the AANA and the SIPC, currently support and promote safe injection practices. Even with existing efforts, patients remain at risk of infection due to lack of knowledge of or engagement with contemporary best practices. Successful adoption of these guidelines will require a renewed, comprehensive, interdisciplinary communication plan to reach patients, professions, education programs, and practice settings (e.g., home, office, clinic, ambulatory surgical center, hospital, school, and correctional facility).

The AANA encourages the FDA to work with other organizations (e.g., CDC, SIPC) to create and disseminate educational materials that inform stakeholders (e.g., manufacturers, accreditors, clinicians, patients) about the proper use of each type of medication container. As infection outbreaks continue to occur due to poor injection practices, coordinated education and research for improvement across all settings and professions are necessary.

Thank you for the opportunity to comment on this draft guidance and collaborate with the FDA on this important issue. Please contact Lynn Reede, DNP, MBA, CRNA, AANA Senior Director, Professional Practice, at (847) 655-1136 or lreede@aana.com with any questions or requests for additional information.

Sincerely,



Juan Quintana, DNP, MHS, CRNA
AANA President

cc: Wanda O. Wilson, PhD, CRNA, AANA Executive Director/Chief Executive Officer
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