May 23, 2014

Stephen Ripley
Center for Biologics Evaluation and Research
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Mr. Ripley:

On behalf of the American Nephrology Nurses' Association's (ANNA) Registered Nurses (RNs), Advanced Practice Registered Nurses (APRNs), and Clinical Nurse Specialists (CNS), we would like to state our support for the Guidance for Industry Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products.

ANNA is a professional nursing organization of over 10,000 registered nurses practicing in nephrology, transplantation, and related therapies. ANNA promotes excellence in and appreciation of nephrology nursing so we can make a positive difference for people with kidney disease.

End Stage Renal Disease patients receive treatment at more than 5,800 outpatient dialysis centers in the United States. These facilities provide care to more than 430,000 hemodialysis and peritoneal dialysis patients and are an example of a health care setting in which rigorous attention to infection control greatly influences the infection-related outcomes of patients. In addition, due to the immunocompromised state of kidney transplant recipients, strict adherence to minimizing and eliminating any potential increased risk of exposure to contaminants must be followed.

ANNA has concerns that if the excess volume in a vial is greater or less than the USP recommended amount, the excesses and deficiencies may result in medication errors and may lead to misuse of leftover drug product or pooling of vials to obtain a single dose. Instances of unsafe handling and injection practices have led to an increased risk of bloodborne illness transmission between patients. By establishing a maximum volume in multiple-dose vials, the healthcare practitioner will be able to decrease the number of vial septum punctures thus reducing the potential for vial contamination. Single-dose vials should not contain a significant volume beyond what would be considered a usual or maximum dose for the expected use of the drug product thus decreasing the potential for exceeding the prescribed dose.

Thank you for the opportunity to respond.

Sincerely,

Sharon Longton, RN, BSN, CNN, CCTC
2014-15 National President