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Nurses Association

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December 30, 2024

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Food and Drug Administration  
Department of Health and Human Services  
3630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2021-P-0893 Supplemental Comment to August 3, 2021,  
Citizen Petition and Petition for Stay Submitted by Sidley Austin LLP on Behalf of  
Vifor (International) Inc., Switzerland**

To Whom It May Concern:

On behalf of the American Nephrology Nurses Association (ANNA), a professional association that represents nurses who work in all areas of nephrology with more than 6,000 registered nurses, we would like to provide a letter of support to Vifor's August 3, 2021, citizen petition (Docket No. FDA-2021-P-0893).

ANNA develops and updates standards of clinical practice, educates practitioners, stimulates and supports research, disseminates knowledge and new ideas, promotes interdisciplinary communication and cooperation, and monitors and addresses issues encompassing the breadth of practice of nephrology nursing. ANNA believes that the demand for quality nephrology patient care will continue to grow in the future, especially with the many changes occurring within health care and, specifically, within the specialty of nephrology. We actively support research to both develop evidence-based practice as well as to advance nursing science.

The citizen petition calls for FDA to prioritize patient safety by permanently reinstating the original names for sucroferric oxyhydroxide and three intravenous (IV) iron products (iron sucrose, sodium ferric gluconate, and iron dextran). In addition, Viofor also requests FDA include steps to implement the changes in the active ingredient name in Drugs@FDA and the Orange Book.

In response, On July 1, 2024, the FDA Center for Drug Evaluation and Research (CDER) announced that it was re-evaluating its determination on the naming of these iron products. ANNA appreciates FDA's willingness to reconsider its previous actions and that, in the meantime, FDA is recognizing the original active ingredient names of these iron products as the agency reviews its decision.

ANNA appreciates your consideration of our comments. If we can be of any assistance on this matter, please do not hesitate to contact me or ANNA's Washington representative, Jim Twaddell ([jwtwaddell@venable.com](mailto:jwtwaddell@venable.com)).

Sincerely,

A handwritten signature in black ink that reads "Nancy Colobong Smith". The signature is written in a cursive, flowing style.

Nancy Colobong Smith, MN, ANP-BC, CNN  
President