



May 9, 2016

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

**RE: FDA–2015–N–5017, Banned Devices; Proposal To Ban Powdered Surgeon’s Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon’s Glove**

To Whom It May Concern:

The American Association of Nurse Anesthetists (AANA) is the professional association representing more than 49,000 Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists in the United States. More than 90 percent of the nation's nurse anesthetists are members of the AANA. CRNAs are advanced practice registered nurses who personally administer more than 40 million anesthetics to patients each year in the United States. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers, pain management facilities, and the offices of dentists, podiatrists, and all types of specialty surgeons.

The AANA welcomes the opportunity to submit comments regarding the U.S. Food and Drug Administration (FDA) proposed rule, “Banned Devices; Proposal To Ban Powdered Surgeon’s Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon’s Glove” (81 Fed. Reg. 15173, March 22, 2016).

**The AANA supports the proposal to ban powdered surgeon’s gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon’s glove to mitigate the adverse events related with these devices, thus promoting patient and healthcare worker safety.**

We appreciate the work that the FDA has completed over many years to thoroughly review the literature and examine the health risks and benefits, environmental impact, and economic impact of the proposal to ban the use of powdered gloves. By eliminating the exposure of the latex protein that is absorbed and concentrated in latex glove powder, the risk of healthcare workers and patients developing latex sensitivity and life threatening allergy is minimized.<sup>1</sup> Powdered exam and sterile gloves are the main source of latex exposure. High-quality, non-powdered low latex or non-latex gloves should be the standard across all healthcare settings, as well as in any setting where exam or sterile gloves are worn in the United States (e.g., home care, dentistry, food preparation).<sup>2</sup>

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<sup>1</sup> Korniewicz DM, Chookaew N, Brown J, Bookhamer N, Mudd K, Bollinger ME. Impact of converting to powder-free gloves. Decreasing the symptoms of latex exposure in operating room personnel. *AAOHN J.* Mar 2005;53(3):111-116.

<sup>2</sup> Latex Allergy Management Guidelines. Park Ridge, IL: American Association of Nurse Anesthetists; 2014.

We thank you for the opportunity to comment and further partner with the FDA on this important issue. AANA is available to communicate relevant materials to our members and consult on any clinical issues, particularly dealing with anesthesia care. Please do not hesitate to contact Lynn Reede, DNP, MBA, CRNA, Senior Director, Professional Practice, at (847) 655-1136 or lreede@aana.com if you have any questions or comments.

Sincerely,

A handwritten signature in black ink that reads "Juan F. Quintana". The signature is written in a cursive, flowing style.

Juan Quintana, DNP, MHS, CRNA  
AANA President

cc: Wanda O. Wilson, PhD, CRNA, AANA Executive Director/Chief Executive Officer  
Lynn Reede, DNP, MBA, CRNA, AANA Senior Director, Professional Practice