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April 20, 2011

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

RE: Docket No. FDA-2011-N-0027 Information Related to Risks and Benefits of Powdered Gloves

Dear Mr. Gadiock,

The Association for Professionals in Infection Control and Epidemiology (APIC) is pleased to respond to the Food and Drug Administration's request for comments on the issue of risks and benefits of surgeons' powdered gloves.

APIC finds very limited scientific evidence that powder on medical gloves, specifically surgeon's gloves, may act to promote infection. However, APIC cannot cite any instance in which powdered gloves offer a unique benefit over powder-free gloves.

In October 1999, the American College of Surgeons published the following statement in its response to the FDA regarding the possible future (at that time) requirement that all gloves be powder free:

The College agrees with the recommendation and believes there is no reason to continue the use of powdered gloves. Indeed, the elimination of powdered gloves will significantly lower the risk of allergic reactions. By making powder-free gloves the standard, the FDA will reduce the incidence of allergic reactions from airborne protein particles carried to the medical staff using them and to the patient. Further, because the protein level in powder-free gloves is much lower, the gloves are less subject to hydration and, hence, retain their barrier qualities.

According to the Association of periOperative Registered Nurses 2011 Latex Guideline it is recommended that as a part of avoiding contact dermatitis the provider should wear powder-free gloves and that powder may provide aerosolization of latex from the gloves or other latex device.

Despite limited evidence in the causation of, or contribution to, infections in patients undergoing surgery, APIC supports the use of powder-free surgeon's gloves in healthcare. APIC would also suggest that the FDA word the proposed warning in plain language for the healthcare workers who might benefit from more plainly-stated guidance.

Thank you for this opportunity to comment on this issue. If you desire any further information, please contact Tom Weaver at 202-454-2602 or Tweaver@APIC.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Russell Olmsted".

Russell Olmsted, MPH, CIC
2011 APIC President