

FDA BANS POWDERED SURGICAL GLOVES

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The US Food and Drug Administration (FDA) today announced it has finalized its proposed ban on powdered surgeon's gloves, powdered patient exam gloves, and absorbable powder for lubricating surgical gloves.

The measure will take effect on January 19, 2017. The ban also applies to similar gloves used in dentistry.

The goal is to "reduce the number of adverse events associated with using powdered gloves," the agency said. The agency rejected arguments that powdered gloves prevent skin problems in the physicians and other workers who use them, such as dermatitis and urticaria. It also dismissed arguments that other gloves are more expensive, saying safety should take precedence.

"The risks to both patients and health care providers when internal body tissue is exposed to the powder include severe airway inflammation and hypersensitivity reactions," the agency noted.

In addition, such particles may trigger an immune response in which granulomas or adhesions form, creating surgical complications.

The FDA also cited a risk of the powder becoming aerosolized.

When inhaled or when it comes in contact with internal tissue during oral, gynecological, rectal or other exams there could be an additional hazard to patients, the agency said.

So far radiographic protection gloves are not included in the ban. Manufacturers in the US will still be allowed to export powdered gloves to countries that permit their use.

Nor does the FDA ban the powder used in the manufacturing process or non-powdered gloves, which include only a trace of residual powder.

During the comment period that preceded today's announcement, the FDA heard from those opposed. Among the objections cited were that hyperhidrosis can make it difficult for physicians to put the gloves on or take them off.

But the FDA said "we have concluded that the benefit of ease of donning or doffing powdered gloves is generally nominal in comparison to the risks posed."

The agency also rejected opponents' arguments that non-powdered gloves promote urticaria.