FDA moves to ban most powdered surgical gloves (Update)

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Federal health officials are moving to ban most surgical gloves made with powder, a feature designed to make them easier to wear, but which actually poses health risks to patients and health professionals.

The Food and Drug Administration said Monday that the powder added to some latex gloves can cause breathing problems, wound inflammation, and scar tissue on internal organs when used during surgery. The agency proposed the ban Monday in a federal filing.

The action is not expected to have much impact on glove supplies or manufacturer sales, according to government research. Most powdered gloves have already been phased out, and only six manufacturers are still registered to make them in the U.S., according to the agency.

"This ban is about protecting patients and health care professionals from a danger they might not even be aware of," said Dr. Jeffrey Shuren, head of the FDA's medical device center.

Public Citizen, the consumer watchdog group, petitioned the FDA to ban powdered gloves in 1998, citing allergic reactions caused by cornstarch powder used in most brands. At the time, the group estimated roughly 75 percent of surgical gloves used in the U.S. contained the powder. Prior to the 1970s, powdered gloves contained talc, another ingredient that was found to be an irritant.

"The fact that it took the FDA 18 years to propose banning powdered

surgical gloves from the market highlights how recklessly negligent the agency is," said Dr. Sidney Wolfe of Public Citizen, in a statement. "There is absolutely no new scientific information today that we didn't have in 1998."

It's only the second time the FDA has proposed a market ban on a medical supply. In 1983, the agency banned fake hair implants intended to conceal baldness, saying the fibers were not effective and could lead to infections and injuries.

The FDA says its proposal on surgical gloves is based on extensive review of scientific literature and public comments, which it began collecting in 2011. Typically the FDA addresses safety issues with medical devices by adding warning labeling or modifying their instructions for use. But the agency concluded that the safety issues with powdered gloves could only be addressed by removing them from the market.

"The ban is also not likely to impact medical practice, because many non-powdered protective glove options are currently available," states the FDA announcement.

The FDA will take public comments on its proposal for 90 days, before moving to finalize the ban.