American Latex Allergy Association

FDA Mulls Health Warning on Powdered Gloves

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.

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Health risks associated with powdered medical gloves ? for professionals as well as patients ? may soon be highlighted on their packages, according to the FDA.

In a draft guidance document for manufacturers, the FDA proposed that powdered surgical and patient examination gloves carry a warning that the products may cause health problems ranging from latex allergies to granulomas and adhesions in patients.

The guidance won?t be formally adopted until after the agency digests comments on the proposal, which it is accepting through April. Technically, guidance documents are not enforceable, but most manufacturers follow their recommendations scrupulously.

According to the draft, the FDA is reacting to reports on adverse effects associated with powdered medical gloves.

In 1997, an FDA study found a range of allergic reactions that could be caused by these products, which include gloves made of natural rubber latex, nitrile, vinyl, and polychloroprene.

The powder particles ? usually cornstarch ? can carry latex molecules from the natural rubber gloves, triggering or exacerbating allergies in some patients and professionals, the FDA found.

Powders on nonlatex gloves have also been the subject of adverse event reports more recently, the FDA indicated, citing more than 30 studies. These include impaired wound healing, inflammation, granulomas, and adhesions in patients.

Some have shown that hospitals switching to unpowdered gloves have reduced allergy development and respiratory problems, the FDA added.

The agency also noted, however, that ?this has not been a universal finding,? and the studies have had significant methodological limitations.

Nevertheless, the agency is proposing that manufacturers include the following warning on glove boxes:

?Powdered gloves may lead to foreign body reactions and the formation of granulomas in patients. In addition, the powder used on gloves may contribute to the development of irritant dermatitis and Type IV allergy, and on latex gloves may serve as a carrier for airborne natural latex leading to sensitization of glove users.?

If the guidance is adopted, manufacturers are urged to place the warning on product labeling within six months.

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