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September 24, 1999

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

Gentlemen:

These comments are in response to your announcement in the Federal Register of July 30, 1999 concerning Surgeon's and Patient Examination Gloves; Reclassification and Proposed rule.

Sincerely,

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Comments to FDA proposed regulations

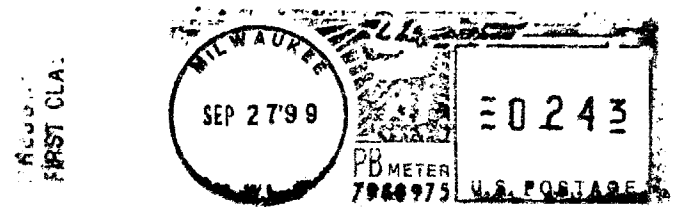
As an Allergist-Immunologist who has been involved in the diagnosis, care and follow-up of between 150 and 250 healthcare workers with latex sensitivity, many of whom became permanently disabled and are lost to the workforce, I applaud the FDA efforts to reduce this potentially devastating problem.

I would point out the following:

1. It is clear that between 6 and 10 percent of the healthcare work force is Type 1 allergic to latex, largely through sensitization of latex antigen on glove powder from high protein (antigen) containing gloves. Some individuals may have become sensitized through inhalation of antigen adsorbed to glove powder or by skin abraded by contact dermatitis and subsequent absorption of latex antigen.
2. The threshold level for initial IgE sensitization by latex antigen(s) is not known. Once sensitized, clinical reactions have been shown to occur at less than 1 microgram per meter^3 of air of latex antigen.
3. Individual immune reactivity may vary and different individuals may be sensitized to one or more latex antigens. Nine different antigens have now been described. Differential sensitization to latex antigens between spina bifida patients and healthcare workers has been demonstrated.
4. Initial sensitization depends on multiple factors including the immune reactivity of the individual, his or her atopic status, the degree of exposure (number of gloves used per day, protein and powder content of the gloves) and degree of ambient exposure.
5. It is clear from the literature that exposure to low protein, low antigen gloves are associated with reduced symptoms and hypothetically with reduced initial sensitization.

Thus, the following comments and suggestions to the FDA proposal:

1. If the powder limit is 120 mg per glove, small size gloves and large size gloves will have the same amount of powder. This suggests that the small size gloves will have excessive powder for donning. To further reduce airborne latex antigen during the donning process, it is suggested that the limit of powder be per gram of glove. This would (a) equalize donning needs and (b) further reduce airborne powder (and antigen) levels. In addition, it should be recognized that there is no information regarding the safety of 120 mg of powder and the amounts of antigen from glove to glove that powder contains.
2. As the threshold for sensitization is not known, the limit of 1200 micrograms of extractable protein per glove limit may or may not reduce the degree of such sensitization. As above, the amount of protein allowed should be per gram of glove rather than per glove. Follow-up evaluation of healthcare populations for levels of initial sensitization and evaluation of subsequent reactions will need to be carried out to determine if the 1200 microgram level is sufficient.
3. It should be noted that with the heterogeneity of the immune response to latex antigens characterization of the specific antigens (Hev b 1 through 9) in the gloves may be needed.



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