

# A.L.E.R.T., Inc.

American Latex Allergy Association

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January 25, 2000

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

Subject: Surgeon's and Patient Examination Gloves; Reclassification  
Docket Number 99D-2335

A.L.E.R.T., Inc. is a not-for-profit national organization whose mission is to create awareness of latex allergy through education and to provide support to individuals who have been diagnosed with latex allergy.

A.L.E.R.T., Inc. supports the work the FDA is doing to improve the safety and quality of medical gloves. We strongly agree that the reclassification of surgeon's gloves and patient examination gloves into a class II (special controls) is warranted.

We ask the FDA to consider the following comments:

1. We agree with the recommendation of no more than 2 mg powder per glove for surgeon's and patient examination gloves labeled as "powder-free".
2. We strongly disagree with the maximum level recommendation of 120 mg powder per powdered glove. As the FDA has stated in this document, there exists a large body of research detailing the adverse effects of powder in medical gloves. Powdered latex gloves have been implicated in occupational disease, specifically latex allergy and occupational asthma. Furthermore, research documents describe how powdered medical gloves increase surgical complications such as granuloma formation and infection and wound healing failure. Glove powders also adversely affect indoor air quality and can be an additive to foods when prepared by persons wearing powdered gloves. We suggest that the recommendation be revised to include a five-year powder reduction plan, so that at the end of this period all medical gloves would be "powder-free".
3. We strongly disagree with the maximum level recommendation of 1,200<greek-m>g protein per NL glove. In this document, the FDA has clearly described the adverse health affects of NL proteins found in medical gloves. We suggest that the recommendation be revised to include further protein reduction over a five-year period.

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4. We ask that the FDA use a "per glove" amount when describing glove powder and protein levels. Stating powder and protein levels, as "per glove" measurements will assist the consumer in understanding the package labeling.
5. We strongly advise the FDA to mandate that the maximum levels of powder and protein be required limits rather than recommended limits.
6. We believe that restrictions on advertising of powdered medical gloves would decrease the demand for this product. We ask that the FDA consider a plan that would limit the advertising of powdered medical gloves.
7. We agree that expiration dating of medical gloves is needed. The label should also include heat and humidity storage recommendations. The expiration and storage information will assist the consumer and insure the effectiveness of the medical glove's barrier properties.
8. In our clinical experiences we have found that the consumer (glove wearer) in many cases does not see or have access to the glove boxes. Some gloves are removed from their original boxes and placed in glove bins. In the workplace, glove boxes may also not be visible when placed in opaque holders. We recommend that the FDA require that medical gloves remain in their original container and prohibit the use of these bins and opaque holders.

We thank the members of the FDA who drafted this document and appreciate the opportunity to provide comment.

Sincerely,

*Diane*  
Diane J. Flanagan  
President

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Date 1-26-00

Sender's Name \_\_\_\_\_ Phone (414) 677-9707

Company ALERT INC

Address 3791 SHERMAN RD Dept./Floor/Suite/Room \_\_\_\_\_

City SLINGER State WI ZIP 53086

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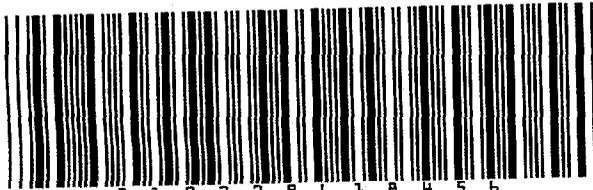
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