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405 William Salesbury Drive
Downingtown, PA 19335
December 28, 1999

Dockets Management Branch (HFA-305)
Food & Drug Administration
5600 Fisher's Lane
Rockville, Maryland 20852

Dear FDA Representative;

I am writing in reference to the proposed rule [Docket No. 98N-0313], which will reclassify all surgeon's and patient examination gloves as class II medical devices. I support and applaud the FDA taking a proactive stance in attempting to reduce the adverse health effects caused by natural rubber latex allergens, with this ruling.

There has been research and documentation in recent years noting the increased prevalence of natural rubber latex allergy due to the use of powdered latex gloves made of hevea natural rubber. Additionally the use of powder in surgical and patient examination gloves has proven to cause adhesions, as well as other medical complications. I have worked in same day surgery nursing, and realize that many patients do not know of the complications that can result from the use of powdered latex gloves. Studies have revealed that surgeons are not compliant in washing the powder from the gloves prior to surgical procedures. Researchers have noted that even the slightest amount of cornstarch powder can cause a potential reaction to latex allergens as well as assist in the development of postoperative complications.

I would like to recommend that manufacturers be regulated to decrease their powder content immediately to a level that is negligible, and to a level agreed upon by ASTM, with six months to comply. I would also like to recommend that powdered surgical and exam gloves be phased out over the next year. Through the re-classification of these gloves, medical gloves would need to meet specific quality controls. These quality controls will enhance the safety of the health care provider using the glove, as well as the consumer receiving the care.

Sincerely,



Marianne G. McAndrew, RN,BSN,CDE

98N-0313

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