MNA

MASSACHUSETTS NURSES ASSOCIATION

October 26, 1999

Docket No. 99D2335
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Dear FDA Representative,

The Massachusetts Nurses Association is the largest professional association for registered nurses in the state, with a membership of approximately 20,000 nurses. MNA represents 18,000 nurses in collective bargaining.

We are submitting comments on:

- FDA Medical Glove Guidance Manual Draft, released on July 30, 1999 and
- 21 CFR Parts 801, 878, and 880, surgeon's and Patient Examination Gloves; Reclassification and Medical Glove Guidance Manual Availability: Proposed Rule and Notice, dated July 30, 1999

The following recommendations are made:

1) FDA standards for medical gloves must require that gloves demonstrate resistance to penetration of blood borne pathogens (BBPs), as judged by passing ASTM F1671 during the entire shelf life of the gloves.
2) FDA must incorporate standards for testing gloves in a way that models typical workplace conditions. In the workplace, gloves may be simultaneously subjected to physical stressors (e.g. stretching, flexing), perspiration, and chemicals or chemotherapy drugs. It is essential that gloves provide an impenetrable barrier to blood borne pathogens under these conditions.
3) FDA must require package labeling to identify chemical accelerators used in the manufacturing process. Chemical accelerators are major source of chemical dermatitis related to glove use.
4) FDA must require package labeling to identify protein content for latex gloves and powder content available for exposure to the user and the patient. The powder-free or powder-less designations promote an erroneous message as powder may be utilized in the manufacturing process
5) FDA must identify suitable alternative materials that protect the safety and health of workers from exposure to sensitizing proteins that may result in life threatening anaphylaxis and from piercing by sharp instruments that result in equally life threatening bloodborne pathogen exposure.

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6) FDA should eliminate comments related air handling systems as this gives the impression that increased ventilation reduces the potential for sensitization and reactions to latex proteins.

Because medical gloves are used to protect against blood borne pathogens (BBP's), it is essential that gloves be tested to ensure that BBP protection is provided. Currently, the FDA does not require a manufacturer to test a glove's resistance to penetration by a BBP. This is unacceptable. A current FDA testing procedure that evaluates leakage of a water-filled glove within 2 minutes, is inadequate for predicting BBP barrier capability. ASTM F1671, which evaluates BBP penetration, is a reasonable test and the FDA should require that medical gloves pass this test thorough out their shelf life.

In addition, current FDA glove requirements fail to consider that in a medical setting, gloves encounter a combination of stressors simultaneously. Frequent glove failures, including tears and leaks (which are often unrecognized until a glove is removed) attest to the fact that current standards are inadequate for protecting workers. The FDA is urged to incorporate medical glove criteria that better typifies the conditions under which gloves are employed to protect workers from blood borne pathogens exposure.

Product labeling is required for many products to identify safety and health issues. Workers who utilize gloves have developed Type IV allergies relate to chemical accelerators. Workers can be tested for sensitivity to chemical accelerators. Since accelerators differ from brand to brand and product to product this labeling would assist workers to identify a glove which would be safe for use.

Workers are becoming familiar with the terminology "low powder and low allergen" in relation to glove selection. The FDA should identify and require the lowest protein and powder content achievable. There is no evidence that 120 mg of powder is a safe level that will protect workers (or patients) from sensitization and/or reactions. Since manufacturers have reached a level of 10mg, the FDA should require the lowest level attainable. The powder and protein content per glove should be clearly identified as a labeling requirement.

Since 1989, additional glove materials have been utilized to protect both workers and patients from exposure to bloodborne pathogens. FDA must include these products in its' comments regarding glove suitability for worker protection in health care settings.

The use of alternative products for protection of workers from exposure to bloodborne pathogens has been addressed by FDA and CDC in the past.

FDA on October 13, 1986

"There is no epidemiological data to indicate that users of vinyl gloves have a higher incidence of blood or fluid borne infections".

CDC on October 18, 1989

"There are no reported differences in barrier effectiveness between intact latex and intact vinyl used to manufacture gloves."

General exhaust ventilation while it may dilute the concentration of latex proteins in a volume of air, it will not serve to eliminate latex proteins from the air inhaled in the work environment. Airborne inhalation of latex proteins is considered the primary source of sensitization. In fact general exhaust ventilation, by design, draws the indoor air past the workers breathing zone permitting inhalation of sensitizing proteins. Local exhaust ventilation i.e.: ventilation at the point of use of the gloves, would serve to lessen the amount of powder available for inhalation. This is method of ventilation is inappropriate in the health care setting where the overwhelming majority of powdered gloves are used.

The Massachusetts Nurses Association shares concerns and supports recommendations of the American Nurses Association, the Emergency Nurses Association, and the Sustainable Hospitals Project at the University of Massachusetts, Lowell related to elimination of powdered gloves, reduced protein content of latex gloves, improved labeling of glove materials and contents and identification of viral barrier protectiveness.

In fact, we believe identification of viral barrier protectiveness of all glove materials to be critical for users of these products to have trust and confidence that the FDA approval process is truly directed at the safety and health of workers in the health care industry and their patients.

Sincerely yours,

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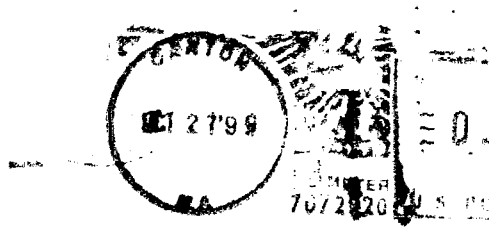

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