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**Dockets Management Branch  
 (HFA-305)  
 Food and Drug Administration  
 Department of Health and Human Services  
 5630 Fishers Lane  
 Room 1061  
 Rockville, Maryland 20852**

**Docket No. (98N-0313)  
 Re: Surgeon and Patient Examination Gloves; Reclassification**

**Dear Sir or Madam:**

**On behalf of our members 500 hospitals, nursing homes, health systems, and other providers, the Health Care Association of New York State (HANYS) appreciates the opportunity to provide comments to the Department of Health and Human Services, Food and Drug Administration (FDA) concerning the proposed regulations to reclassify all surgeon and patient examination gloves as Class II Medical Devices.**

**HANYS supports the intention of Health Care Financing Administration's (HCFA's) proposed rule to reduce the adverse health effects from allergic and foreign body reactions caused by Natural Latex (NL) protein allergens and glove powder. HANYS presents the following comments and recommendations regarding the proposed requirements.**

**COMMENTS**

**PART 801—Labeling  
 Section 801.437 User labeling for devices that contains natural rubber.**

**(d)(1) (d)(2) FDA's proposed manufacturer labeling requirement for powdered surgeon and patient examination gloves containing NL to require the device labeling: "Caution: This product contains natural rubber latex which may cause allergic reactions."**

**HANYS recognizes the FDA's need to enact such manufacturers labeling requirements as a first step towards reducing allergic reactions.**

**The FDA recommended the proposed requirement and powder levels based on the belief that such levels can be achieved by the industry. However, we believe the FDA, in moving forward in this area, is void of appropriate scientific data to support such decision-making and the guidance document titled, The Center for Devices and Radiological Health, FDA, "Medical Glove Guidance Manual," as revised under 880.6250. The proposed rule and guidance document does not provide a reasonable level of assurance of safety, effectiveness for health care providers and patients, or an**

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acceptable justification in terms of dollars. In addition, we suggest future FDA rulemaking centered on the reduction of powder and protein levels must be accomplished by scientific study and methods that do not compromise the availability of barrier properties of surgeon and patient examination gloves, or the safety of individuals employed in the health care industry.

## RECOMMENDATIONS

### The FDA should:

- I. Delete specific provisions referenced in Section 801.440(a), (b), and (c), which recommend synthetic and powdered surgeon gloves and powdered patient examination gloves, contain no more than 120 milligrams (mg) of powder and 1,200 micrograms (ug) of extractable protein per glove. Specifically, FDA must make available sufficient scientific data that would support the proposed limits of glove powder, assure a reasonable level of safety and effectiveness, and justification in terms of expenditures.
- II. Initiate further scientific study into what constitutes acceptable minimum and maximum allowable levels of glove powder for synthetic and powdered surgeon gloves and powdered patient examination gloves.
- III. Convene as part of the negotiated final rulemaking process a committee that includes both manufacturing industry and health care industry representatives. We believe such a committee is warranted and needed to ensure an acceptable balance between donning requirements and reducing the risks of adverse health effects exists.

### Specific Request for Comments

The FDA requested comments on the timeframe for implementation of the proposed rule. HANYS concurs with the FDA that given the changes in the production, technology and labeling, as well as the need to address adverse health concerns associated with medical gloves that a one year effective date is not realistic, and if chosen could possibly result in a shortage of medical gloves. We are concerned with the FDA's proposed two years effective date for implementation, as the FDA has yet to provide the health care industry with valid scientific data and evidence to validate the minimum and maximum allowable levels of glove powder for synthetic and powdered surgeon gloves and powdered patient examination gloves. Because there is insufficient data in this area, the FDA is not able to ensure an acceptable balance between donning requirements and reducing the risks of adverse health effects.

## RECOMMENDATION

- I. The FDA should remain consistent with its own policy governing reclassification. The policy states that "regardless of whether data before the agency are past or new data, the "new information" on which any reclassification is based is required to consist of "valid scientific evidence," as defined in section 513(a)(3) of the act (21 U.S.C. 360c(a)(3) and 21 Code of Federal Regulations (CFR) 860.7(c)(2) CFR).

- II. The proposed timeframe for implementation of the regulations should be delayed until valid scientific data substantiates proposed acceptable protein and powder limits on surgeon and patient examination gloves.**

#### **COMMENTS**

The FDA requests comments on the feasibility and desirability of additional labeling requiring manufacturers to state the primary ingredients in glove powder in the product labeling. HANYS supports the FDA in the goal of reducing exposure to airborne allergens through the addition of manufacturer labeling requirements. However, we do have concerns surrounding manufacturer efforts to produce powder-free gloves with satisfactory donning properties. Such products will require additional manufacturing processes and controls by the FDA, including increased quality controls and regulatory surveillance measures, to prevent deleterious effects.

The FDA has stated costs associated with this rulemaking would be passed through to health care facilities in the form of higher prices. The FDA has not defined what incentives would be provided for facilities to accelerate the use of these products.

In addition, we are concerned with the FDA's desire to put forth provisions in this rulemaking which allows manufacturers to establish an initial tentative shelf life up to a certain duration based on accelerated aging data. The FDA by its own admission has been unable to determine whether any validity stability study protocols exist that employ accelerated aging methodologies that are predictive of glove shelf life.

#### **RECOMMENDATION**

**The FDA should:**

- I. Initiate further cost and impact analyses on health care facilities (i.e., hospitals, nursing homes, and the non-for-profit facilities considered under the rule as "small entities") as a result of the manufacturing process associated with the production of powdered surgeon gloves, powdered patient examination gloves, and powder-free gloves. Specifically, manufacturers efforts to produce products and powder-free gloves with satisfactory donning properties will be subject to FDA increased quality controls and regulatory surveillance measures.**
- II. Provide scientific evidence and data to the health care industry that defines clearly an acceptable balance between donning requirements and that reduced risks of adverse health effects exists.**
- III. Delay promulgation of new regulations until scientific data and evidence can be provided to the health care industry that address outcomes associated with the examination of the impact of proposed powder limits on barrier properties and shell life of natural rubber latex.**

- IV. Clarify what incentives will be provided to health care facilities in an effort to accelerate the use of synthetic and powdered surgeon gloves and powdered patient examination gloves which contain no more than 120 mg powder and 1,200 ug of extractable protein per glove and gloves labeled as "powder-free."**

#### **COMMENTS**

The FDA invited comments on the issue of whether the recommended limits placed on powder and protein proposed in this rule should be recommended or required limits. Based on the myriad of issues, which still require FDA clarification, HANYS does not believe it is acceptable for the FDA to propose any required limits regarding powder and protein levels in this rule.

#### **RECOMMENDATION**

**FDA not include in the final rule any required limits regarding powder and protein.**

#### **COMMENTS**

The FDA is considering requiring facilities to use a special air handling systems at the point of use for those facilities using powdered surgeon and patient examination gloves with powder levels over 120 mg per glove, regardless of glove size. HANYS views such requirements as overly burdensome, duplicative, and without justification as such requirements will result in increased health care costs to facilities. Health care facilities already have air handling systems, and High Efficiency Particle Emission (HEPA) filtration units as a supplement to other engineering controls. In addition, there are many rooms that meet the criteria for negative pressure and air exhausted to the outside or HEPA filtration that would eliminate the need for a proposed special air handling system.

#### **RECOMMENDATION**

**FDA not require health care facilities to use special air handling systems at the point of use.**

HANYS appreciates the opportunity to provide comments on these important standards. Many questions exist surrounding the manufacturing and usage of both natural rubber latex and nonlatex (synthetic) products. There exist a need for additional scientific data that is conclusive regarding whether calcium carbonate powder, used as an alternative, is less harmful or more effective in reducing natural rubber latex allergic reactions. We remain concerned that chemicals which are used in the production of both natural rubber latex and nonlatex (synthetic) products could be cross reacting on patients and health care employees, thereby complicating research in this area.

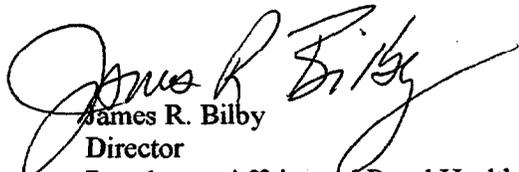
Implementation of this regulation will impose potentially astronomical costs on health care providers and create a tremendous regulatory burden with many compliance issues. It is unclear that manufacturers have the ability to meet an increased demand for powder-free/non-latex products that would be created by this regulation. Similarly, we are concerned that creating a sudden and large demand for such products will contribute to the production of mass quantities of low-quality products. In addition, there does exist research that indicates synthetic or non-natural rubber latex products may not perform as effectively as natural rubber latex potentially increasing the risk of infection and breakage of barrier prophylaxes. Such

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serious changes in FDA policy should not be made when it is not supported by available and credible scientific evidence. Given the inconclusive state of research on this issue, HANYS believes the FDA's action is premature.

HANYS suggests an alternative approach to this proposed rule. To promote a "latex responsible" environment, we suggest the FDA modify its guidance document and combine that action with continued research on the outstanding issues, as well as education/training initiatives to health care facilities. We believe these actions collectively would serve as an effective alternative approach to reducing the adverse health effects from allergic and foreign body reactions caused by NL protein allergens and glove powder on individuals.

Sincerely,

  
James R. Bilby  
Director  
Regulatory Affairs and Rural Health

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