January 8, 2000

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Food and Drug Administration
Room: 1061
Dockets Management Branch HFA-305
5630 Fishers Lane
Rockville MD 20852-0001

Dear Madam or Sir,

These comments are in response to Docket No. 98N-0313

1. *FDA requests comments on the timeframe for implementation of the proposed rule considering the need for changes in production, technology, and labeling, as well as the immediate need to address adverse health concerns associated with medical gloves. Although FDA prefers a 1-year effective date, FDA is proposing a 2-year effective date based on indications from industry that the necessary changes could not be made in 1 year and that a shortage of medical gloves could result.*

I am a medical technologist working in a large hospital laboratory and have a type IV latex allergy. As a result of a seminar presented by the Clinical Laboratory Managers Association, we have been using exclusively non-powdered, low protein (less than 50 micrograms) gloves for several years. Our supplier is Allegiance and the gloves are already available. Since there would need to be increased production and not a totally new process, I believe a 1-year effective date is best and could prevent many more health professionals from developing this allergy that endangers lives and has caused many to have to abandon their lifelong careers.

2. *In the proposed guidance document, FDA recommends a limit of no more than 120 mg powder per powdered glove, regardless of size, as the maximum level in order to reduce exposure to particulates and airborne allergens. FDA requests comments on the recommended limit with regard to the minimum level of powder needed for adequate donning of gloves.*

Our powder-free gloves are very easy to put on (Allegiance). I have personally been using them in a close fitting size and find that they are just as easy to put on as powdered gloves and not nearly as messy or hazardous. As a laboratory professional, I change gloves a minimum of 20 times a day with ease.

3. *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.*

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It is helpful to individuals to know the substances with which they come in contact on a regular basis. A concern is increased costs associated with such a requirement. With reduced Medicare reimbursement, even large city hospitals are struggling to keep their doors open and this is an extremely high volume purchase.

4. *In the proposed guidance document, FDA is recommending no more than 2 mg powder per glove, regardless of size, as the recommended powder level for those surgeon's and patient examination gloves labeled "powder-free." FDA requests comments on the proposed limit. FDA is also seeking comments on the possible impact of this powder limit on barrier properties and shelf-life of NL gloves.*

Shelf life is of little concern to our hospital due to the rapidity with which we replace our stock. Our usage is so large that nothing sits on a shelf for any length of time.

5. *FDA is also considering a future requirement that all surgeon's and patient examination gloves marketed in the United States be powder-free. FDA requests comments as to whether a continued need for powdered gloves exists, and, if so, the reason for this need. Comments on the feasibility of such restrictions.*

I strongly support the banning of powdered gloves. It is my opinion that, no need exists for powdered gloves and their continued use is mainly by individuals who don't like to change what they are used to. I truly believe that this is the only way to reduce the airborne latex particles that endanger so many of us and continue to sensitize many more health care professionals. Again, the powder-free latex gloves we use are wonderful and easy to don.

6. *FDA considered restrictions on the sale (advertising), distribution, and use of powdered surgeon's and patient examination gloves. FDA is seeking comments on the feasibility of such restrictions.*

I strongly support such a move. Most opposition will probably be from the glove manufacturers who have a financial interest in this issue and don't realize or don't care how many individuals' lives and careers have been ruined by latex allergy.

7. *In the proposed guidance document, FDA is recommending an upper limit of no more than 1,200 μg protein per NL glove, regardless of size, as the maximum level for NL surgeon's and patient examination gloves. FDA is seeking comments on the proposed recommended limit.*

The gloves we use have less than 50 micrograms protein (I recently checked after being diagnosed with latex allergy). I think your proposal is too high and the incidence of latex allergy will continue to rise.

9. *FDA also invites comments on the issue of whether the recommended limits on powder and protein proposed in this rule should be recommended limits or required limits.*

The recommendations should be required because it is a severe health issue. The number of people demonstrating latex allergy has risen dramatically since Universal Precautions went into effect and continues to rise. Compliance must be mandatory for the desired effect.

10. *FDA considered allowing manufacturers to establish an initial tentative shelf-life up to a certain duration based on accelerated aging data, provided that manufacturers initiate concurrent real-time shelf-life studies to confirm and extend the tentative shelf-life. FDA has been unable, however, to determine whether any validated stability study protocols exist employing accelerated aging methodologies. The agency invites comments or information on the availability of accelerated aging stability study protocols which are predictive of glove shelf-life. If convincing information concerning such protocols is available, FDA may incorporate such an approach in a final rule.*

No comment.

11. *FDA considered requiring the use of a special air handling system at the point of use for those facilities using powdered surgeon's and patient examination gloves with powder levels over 120 mg per glove, regardless of glove size. FDA is seeking comments on the appropriateness of this restriction.*

This would not be necessary if powdered gloves were banned as they should be. However, if the FDA chooses not to ban powdered gloves, the air handling requirement would serve as a financial incentive for converting to powder-free gloves although I question the ability of such a system to lower powder and protein concentrations sufficiently for the latex allergic patient.

12. *FDA seeks comments as to whether a provision permitting affected persons to request exemptions or variances from the labeling requirements or restrictions on distribution and use proposed in this rule should be added.*

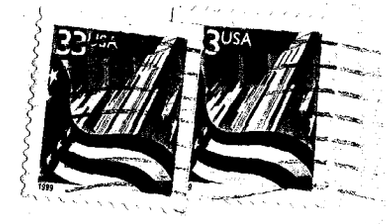
This is a serious health issue and no exemptions or variances should be allowed.

Sincerely,

Karna Williams

Karna Williams
808 S Redbud
Broken Arrow, OK 74012

Karna Williams
808 S Redbud Ave
Broken Arrow, OK 74012



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