TILLOTSON HEALTHCARE CORPORATION

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January 26, 2000

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

Re: Docket No. 98N-0313: Surgeon's and Patient Examination Gloves; Reclassification

Dear Madam or Sir:

These comments are submitted by the Tillotson Healthcare Corporation (THC) in response to the Food and Drug Administration's (FDA) proposed rule to reclassify medical gloves as Class II medical devices. See 64 Fed. Reg. 41,710 (July 30, 1999). THC is a manufacturer of medical gloves with plants in New Hampshire and Malaysia. THC manufactures both Examination gloves and Surgeons gloves using both Natural Rubber and Synthetic materials. THC's CEO, Thomas N. Tillotson Chairs both the HIMA Latex Issues Working Group and the ANSI MD156 Working Group 9.51 on Standards for Gloves for Dentistry. THC's Vice President of Research and Development, Dr. Frank W. Perrella, Chairs the ASTM D11.40 Working Group on Residual Protein Test method development, Working Group on Chemical Accelerator residual test method development and Working Group on Human Draize test standardization for gloves as well as being active on the other ASTM committees dealing with Glove Standards, Glove powder Residual testing and Shelf life aging protocols. Thus we feel that THC is highly qualified to comment on these proposed rules that relate directly to most of these activities.

First, THC would like to commend the FDA for producing a new set of rules that takes into account the changes in medical glove technology that has occurred of the last ten years since FDA's initial glove regulation. It is THC's intention in these comments to suggest revisions that

98N-0313

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we believe will improve the rule to make it more easily comprehensible to consumers, implementable by manufacturers and broadly enforceable by the agency.

Second, THC supports the comments submitted by the Health Industry Manufacturers Association (HIMA) and would incorporate by reference all sections therein as part of THC's comments. In addition, THC would expand upon HIMA's comments in the following sections:

I. In Addition to not Including ASTM Consensus Standards in the Proposed Rule, the Proposed Rule Also Fails to Take Into Account the Consensus Standard ANSI/ADA Specification #76-99, Natural Rubber Gloves for Dentistry.

The subcommittee 9 on barrier products working group on Gloves (WG9.51) of ANSI MD-156 published a standards for Natural Rubber gloves for Dentistry in 1999 that also considered and addressed the issues of Protein limits for all gloves and Powder limits for powder free gloves. This committee, composed of representatives from industry, academia and the clinical community, decided that a per unit protein limit was appropriate and set a consensus limit of 200 micrograms/gram of glove. The committee discussed and discarded the concept of a per total glove limit as proposed by the Rule. For consideration at a future meeting is the conversion of the per gram basis to a per surface area basis consistent with the ASTM medical glove Standards.

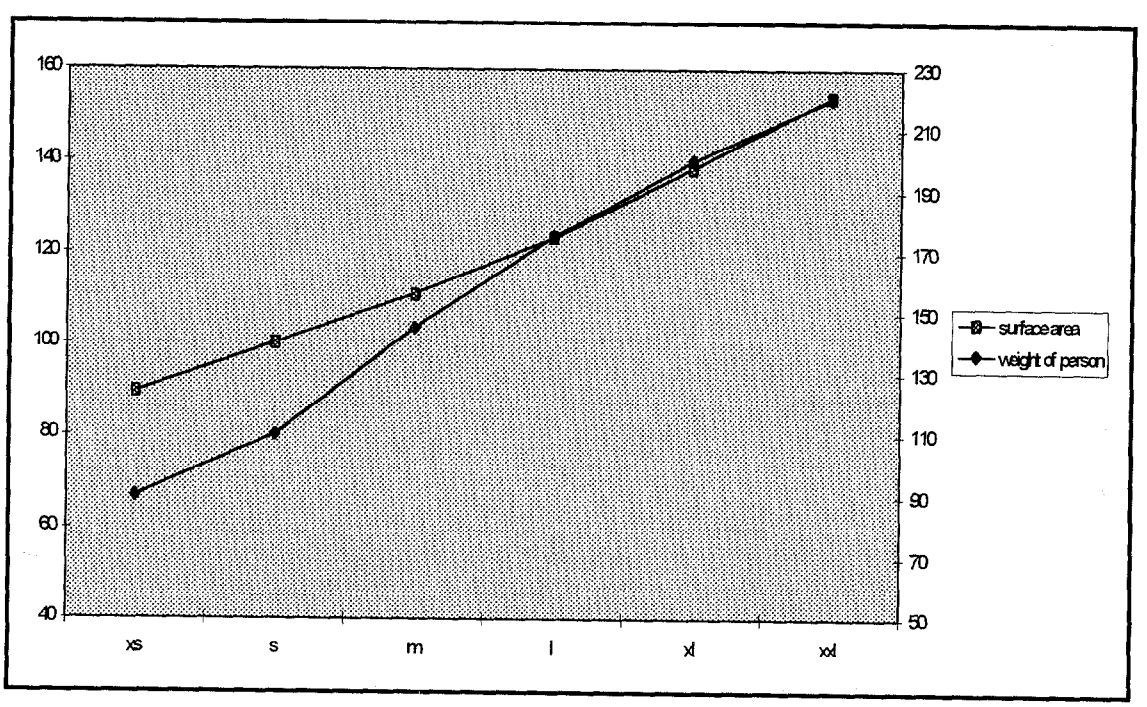
A. FDA Should Adopt ASTM's Protein Standards.

The proposed rule recommends a maximum residual protein limit of 1200 micrograms (μg) of extractable protein per glove. ASTM's protein standards, in contrast, take into account the surface area of the glove. Specifically, ASTM standards D3577-99 and D3578-99 recommend a maximum aqueous soluble protein content of 200 μg per square decimeter of total glove area. For the reasons set out below, THC believes the proposed rule should be modified to incorporate ASTM's protein standards.

In the first instance, and in addition to the concerns raised by HIMA, THC objects to FDA's per glove approach because it would erase the numerology that consumers of gloves currently understand regarding latex allergy issues. Virtually all consumers recognize that a "less than 50.." label represents a glove that is relatively "low" in protein. Likewise, higher levels have taken on meaning to consumers as they weigh their needs against the attributes of a specific product. It was this concern in large part that lead ASTM to adopt the protein level per square

decimeter rationale as this unit of measurement not only addresses the need to more accurately describe a thicker heavier glove, but it coincidentally maintained the same numerology for the common examination glove. For example, glove products with a protein limit of 200 μg/g approximates 200 μg/dm², and similarly the 50 μg/g limit approximates 50 μg/dm². THC, based on THC's knowledge of the user population, strongly urges the FDA to adopt ASTM's Standards approach because the FDA's per glove numerology would cause tremendous confusion among consumers without achieving any recognizable benefit.

Further, in support of HIMA's comment on biological relevancy, THC would like to point out that glove size is proportional to body mass. THC believes that this further supports the concept that a per surface area limit is more relevant for a systemic response such as Type I allergy than a per glove protein limit..



B. FDA Should Adopt ASTM's Powder Standards.

THC would like to note, in addition to HIMA's comments on the powder limits, that the current ASTM standards for powdered gloves contain a step down provision for residual powder over 2 years that would reduce the allowable powder level to significantly less than that proposed by the FDA. The ASTM step down schedule for examination gloves is 20 mg/ dm^2 (1st yr.), 15 mg/ dm^2 (2nd yr.), and 10 mg/ dm^2 (3rd and final yr.). For example, a 7 gram (approximately 7 dm^2 surface area) examination glove would step down from 140 mg per glove to 105 mg per glove to 70 mg per glove (7 dm^2/glove x 10 mg/ dm^2 = 70 mg/glove) in 2 years. Similar evaluations for other types of medical gloves demonstrate both the practical utility of the per surface area methodology and the consumer benefit from lower targeted powder limits.

II. THC Questions the Need for New Labeling.

While THC supports HIMA's comments regarding the Rule's labeling requirements, THC would go further and support conformance to ASTM Standards in place of labeling. The Rule proposes making medical gloves come under the controls of a Class II device. Under those controls, FDA has the power to require performance standards. As noted in prior sections, ASTM has set out the basis for those elements of performance standards with which this Rule is concerned. Thus FDA should be able to simply require conformance to ASTM for this Class II device. Were that to be implemented, the need to relabel could be obviated. FDA does not require that the label contain statements as to other required conformances (water leaks) and FDA has already promulgated regulations for a cautionary statement relative to latex proteins. The elimination of the need to relabel would have the benefit to the consumer of removing a major impediment to the time to implement this Rule.

III. Responses to FDA's Specific Questions

In the proposed rule, FDA requests comments on 12 specific issues. THC would like to add to HIMA's response to these 12 questions as given below:

Question 1 -- Implementation timeframe. If FDA determines that new labeling is required, THC support's HIMA's comments regarding implementation timeframe as in HIMA's Section V . However, THC would support a shorter time frame of 12 months if new labeling were not required.

Question 2 -- Recommended powder limit. THC would like to note that the minimum amount of powder required for adequate donning is a function of the glove's surface morphology and composition. Technologies such as polymer coating the inside of the glove can reduce the need for total powder to less than 20% of FDA's recommended limit of 120 mg per glove. THC would urge FDA to consider an alternative "low powder" claim limit of less than 15 mg per glove (2.5 mg/dm^2) as was done with residual protein limits. The "low powder" label would establish a target such that the market place would encourage manufacturers to develop "low powder" technologies. Thus, if THC's recommendations were adopted, a glove that met the ASTM limits for powder would not need to be relabeled, but a manufacturer who could meet this "low Powder" limit could claim on the box that the glove contained less than 2.5 mg/dm^2 of total powder.

Question 8 -- Feasible alternative approaches to achieve FDA's objectives. THC would urge FDA to incorporate use of the newly standardized ASTM D 6499 ELISA Inhibition test for Total Antigenic Proteins into the Rule. Not only, as pointed out in HIMA's comments, would this allow manufacturer's to further refine their processes to reduce potential allergen content, it would facilitate the implementation of new technology such as enzymatic digestion of latex proteins in the latex itself. Using this technology, manufacturers can preprocess latex right in their plant or from producers in such a way that 95% or greater of the protein is rendered non antigenic. Natural rubber latex products made from enzyme treated latex would benefit the consumer by reducing the potential risk of exposure to latex protein antigens. Since, unlike the ASTM Lowry, the ELISA Inhibition test is based on antigenic protein measurements, it is the required test to identify and control this effect. By allowing use of either the ASTM Lowry or the ASTM ELISA Inhibition to substantiate conformance with the Rule, FDA would allow the broadest range of approaches to meet its objectives.

Question 9 -- Recommended versus required powder and protein limits. THC would like to point out that while there is insufficient scientific basis to require a performance limit on proteins and powder per se, the use of the appropriate ASTM standards as required performance standards could allow FDA to, in effect, make these required limits instead of recommended limits and avoid the issues raised by HIMA in its comments. Should FDA decide that the fact that ASTM has made the protein limits "recommended" is an impediment to adoption of this approach, FDA could work with ASTM to revise the standard accordingly.

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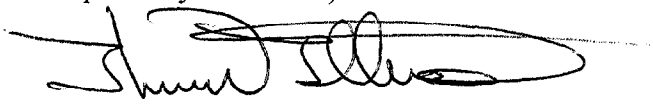
THC appreciates the opportunity to provide comments on FDA's proposal to reclassify medical gloves as Class II medical devices. Should you have any questions on the information presented in this document, please do not hesitate to contact us.

Respectfully submitted,



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