HIMA
HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

JAMES S. BENSON
EXECUTIVE VICE PRESIDENT, TECHNOLOGY AND REGULATORY AFFAIRS

9645 '00 JAN 27 P4:01

January 27, 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 Health Industry Manufacturers Association (HIMA) 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). HIMA is a Washington, D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members manufacture nearly 90 percent of the $55 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $130 billion purchased annually around the world.

## I. HIMA Does Not Oppose Reclassification, But Questions the Scientific Basis Used to Support FDA's Determination of the Risk Associated With Medical Gloves.

FDA's proposed rule would reclassify medical gloves from Class I (general controls) to Class II (special controls). The specific special controls proposed are (I) a new guidance document entitled "Medical Glove Guidance Manual" and (ii) new user labeling requirements including proposed caution statements and an expiration dating requirement for all medical gloves.[1]

[1] HIMA notes that, while the text of the proposed rule does not address the reclassification of glove liners, the Medical Glove Guidance Manual indicates that FDA proposes to reclassify these devices from Class I to Class II. Medical Glove Guidance Manual at 3-5. HIMA recognizes that FDA considers glove liners to come within the classification regulation for surgeon's gloves, 21 C.F.R. § 878.4460. However, HIMA believes that glove liners should be classified separately from surgeon's gloves, and should remain in Class I, because they contain neither latex nor powder.

World Leaders in Health Care Innovation
1200 G STREET, N.W., SUITE 400
WASHINGTON, D.C. 20005-3814
(202) 783-8700 FAX (202) 783-8750
http://www.himanet.com

98N-0313

C57

HIMA does not oppose reclassification of medical gloves from Class I to Class II. Indeed, HIMA recognizes that, in certain respects, much of the medical glove manufacturing industry already functions in a Class II environment. For example, many medical glove manufacturers already operate under Class II design controls, and such controls offer certain benefits to glove users. Furthermore, appropriate performance standards already exist for medical gloves, and most medical glove manufacturers follow these standards.[2]

HIMA notes, however, that, in support of reclassifying medical gloves from Class I to Class II, FDA states that it has "reevaluated its classification in light of medical science . . . [and that] new, publicly available, valid scientific evidence demonstrates that these gloves should not remain in Class I." 64 Fed. Reg. 41,714. FDA expresses concern over a number of risks allegedly associated with medical gloves, including the potential that natural latex (NL) protein allergens, bound to glove powder, may provoke respiratory allergic reactions. 64 Fed. Reg. 41,712. As described below, HIMA questions the scientific basis used to support FDA's determination of the risk associated with medical gloves.

In assessing the risks of airborne NL proteins, HIMA is concerned that FDA may not have taken full account of what is, at best, a conflicting body of scientific evidence. Indeed, FDA itself observes that "no systematic epidemiological data exist to identify the risk of airborne NL protein allergens." 64 Fed. Reg. 41,717. HIMA notes, for example, that FDA does not appear to have considered certain recent well-controlled studies that are contrary to the agency's position. For instance, a recent well-controlled epidemiological study conducted by the National Institute of Occupational Safety & Health (NIOSH) at Exempla St. Joseph's Hospital in Denver compared the latex prevalence rates in a group of employees that wore latex gloves with a group that had never worn gloves. Over 500 subjects were included in the study. The investigators took air samples, analyzed serum for latex antibodies, collected medical information, and evaluated possible risks associated with the use of gloves. Health Hazard Evaluation Report (H.H.E.R.) No. 98-0096-2737.

The NIOSH study found no statistically significant difference in the latex sensitization rates between the group that wore gloves and the group that did not. Furthermore, no association was found between latex sensitization and the length of time gloves were worn or the number of gloves worn daily. Likewise, there was no increase in respiratory symptoms among the group of persons that was sensitized. The study concluded that "neither current nor past occupational latex glove use was a significant risk factor for the development of latex sensitization." H.H.E.R. No. 98-0096-2737 at 9.

The results of the NIOSH study also contradict FDA's statement that "decreased exposure to glove powder will decrease the prevalence of adverse health effects" 64 Fed. Reg. 41,710. Indeed, the NIOSH study found no difference in latex sensitization between people wearing powder-free

---

[2] See, e.g., ASTM D3577, D3578, D5151, and D5250.

gloves and those wearing powdered gloves. H.H.E.R. No. 98-0096-2737 at 6. Despite the use of powdered latex gloves, there was no increase in the latex prevalence rate among the clinical workers. In fact, the sensitivity rate for non-clinical workers was higher than for those working in the clinical areas where gloves were used. Id.

HIMA also challenges the conclusions that FDA draws from its analysis of Medical Device Reports (MDRs). FDA states that between August 15, 1996 and August 15, 1997, it received 330 NL allergy MDR reports associated with medical gloves, which included reactions of 435 persons. 64 Fed. Reg. 41,717. Although FDA acknowledges that these reports are not a representative sampling and are "unconfirmed," the agency nonetheless concludes that "these data may provide a reasonable measure of the magnitude of the existing risk." Id. In HIMA's view, however, FDA's MDR report analysis relies on assumptions that result in a greatly exaggerated assessment of the risk associated with airborne NL protein allergens.

For example, FDA assumes that all 435 persons had been using powdered gloves, when, in fact, some may have been using powder-free gloves. In addition, FDA assumes that, due to under reporting, the number of reported NL allergy adverse events, i.e., 435, represents only one percent of actual adverse events. As such, FDA reaches the estimate that "allergic reactions associated with medical gloves could represent as many as 43,500 allergic incidents during the 12-month period." 64 Fed. Reg. 41,717.

However, the assertion that MDR reports may be under reported by 99% is based upon a general statistic used by FDA (see 64 Fed. Reg. 41,717), and is probably not accurate in this area, given the level of public attention that recently has been focused on medical glove-related health concerns. Indeed, considering the intense publicity surrounding latex gloves in 1996 and 1997, the probability that allergic reactions were under reported by 99% is extremely remote. In fact, many of the prevalence studies cited by FDA itself demonstrate that, if anything, latex complaints are over reported.[3] Moreover, it also is likely that a significant percentage of the 435 MDR reports concerned matters other than latex allergy. Indeed, MDR reports sometimes are based on little more than self-diagnosis and, in the case of latex allergy, clinical determination is very difficult, and over-diagnosis is common.

Finally, HIMA questions the scientific basis underlying FDA's estimate of the mortality rate associated with the use of medical gloves. The agency assigns a 2% mortality rate to medical glove

---

[3] For example, many persons who believed they were latex allergic were found not to carry the latex antibody when tested by serum (i.e., blood) tests. See, e.g., Kaczmarek, R., et al., "Prevalence of Latex-specific lgE Antibodies in Hospital Personnel," Annals of Allergy, Asthma & Immunology, 76:51-56 (1996); Kibby, T., et al, "Prevalence of Latex Sensitization in a Hospital Employee Population," Annals of Allergy, Asthma & Immunology, 78:41-44 (1997); and Lagier, F., et al, "Prevalence of Latex Allergy in Operating Room Nurses," Journal of Allergy and Clinical Immunology," 90: 319-22 (1992).

users, because this is the mortality rate associated with anaphylaxis. 64 Fed. Reg. 41,718. However, the fact is that there have been no confirmed reports of deaths due to the use of medical gloves. Indeed, HIMA believes that any mortality rate assigned to medical gloves should take into account the actual history of medical glove usage, rather than relying on the anaphylaxis mortality rate. Furthermore, in HIMA's view, using the 2% mortality rate associated with anaphylaxis probably is inappropriate, because anaphylaxis cases typically are associated with ingestion or injection of allergens. Thus, if the anaphylaxis mortality rate is used at all, it should be adjusted to account for the extremely rare case of anaphylaxis due to exposure to an inhalant.

In sum, for the reasons stated above, HIMA questions the scientific basis used to support FDA's determination of the risk associated with medical gloves.

## II. The Proposed Rule Fails to Take Into Account Consensus Standards.

In HIMA's view, the proposed rule inappropriately disregards certain relevant industry consensus standards. As described below, FDA's proposed protein and powder limits are inconsistent with ASTM standards. ASTM's protein and powder limits, which FDA participated in developing, have been finalized, and, in HIMA's judgment, the proposed rule should be modified to incorporate them.

Indeed, HIMA believes that FDA's failure to utilize ASTM's protein and powder limits runs counter to Congressional intent in enacting the Food and Drug Administration Modernization Act of 1997 (FDAMA), under which FDA was given authority to "recognize" consensus standards and accept manufacturers' declarations of conformity with such standards as a means of satisfying a premarket submission or other relevant agency requirement. 21 U.S.C. § 360d(c). While FDA is not bound by FDAMA to recognize all aspects of the ASTM standards, the clear intent of FDAMA is that FDA rely more heavily on the content and concepts of consensus standards. This is clear from the Office of Device Evaluation's premarket initiatives in the form of the "Guidance on the Recognition and Use of Consensus Standards" and "New 510(k) Paradigm" guidance.

### 1. 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 and D3578 recommend a maximum aqueous soluble protein content of 200 μg per square decimeter of total glove area. For the reasons set out below, HIMA believes the proposed rule should be modified to incorporate ASTM's protein standards.

As a threshold matter, HIMA objects to FDA's per glove approach because medical gloves vary considerably in size in order to properly fit the user. These different sizes of gloves necessarily contain differing amounts of protein. FDA's approach of imposing the same protein limit on all

gloves -- regardless of their size -- fails to take into account this fundamental fact recognized by ASTM. Indeed, during the development of its protein standards, ASTM initially considered a per glove limit, but ultimately rejected such an approach, because it ignores the critical factor that the amount of protein in a glove necessarily varies, depending upon the glove size.

Furthermore, HIMA believes that FDA's proposed 1200 μg per glove protein limit could cause significant consumer confusion. For example, under a per glove approach, the widely accepted and well understood "less than 50 μg per gram" lower limit label would have to be changed to a different numeric value, depending upon the size of the glove. Thus, a small glove, e.g., a 6 gram glove, with a protein content of 50 μg per gram, would have to be labeled as 300 μg/glove, whereas a large glove, e.g., a 10 gram glove, with a protein content of 50 μg per gram, would have to be labeled as 500 μg/glove.

HIMA believes that ASTM's μg per unit area approach also would be more biologically relevant than FDA's per glove protein limit. Indeed, a maximum protein limit for all gloves, regardless of size, presumes that there is a threshold for latex Type I allergy that is based on total protein content and is independent of body weight and surface area. In reality, however, most biological immune responses are dose or concentration dependent. As an example, an individual with hand eczema and skin fissures probably would be more likely to have a reaction to a higher concentration of a substance that is localized to a skin surface than to a lesser dose spread over a larger skin area, even though the total amount of the substance is constant. Thus, from a biological standpoint, establishing a μg per unit area protein limit, rather than a per glove limit, is considerably more sound.

2. FDA Should Adopt ASTM's Powder Standards.

Under the proposed rule, a 120 mg per glove powder limit would be applicable to all medical gloves, regardless of size. However, as is the case with protein content, ASTM has developed powder standards that are based on glove surface area. Specifically, ASTM has approved powder limitations for powdered gloves in three FDA-recognized consensus standards, D3577, D3578, and D5250, for rubber surgical gloves, rubber examination gloves, and polyvinyl chloride examination gloves respectively and also in the ASTM standard for nitrile examination gloves, D6319.[4] For the reasons set out below, HIMA recommends that FDA adopt ASTM's surface area-based limits, in place of the proposed 120 mg limit.

---

[4] The powder limit approved for the surgical glove standard (D3577), based on ASTM Task Group recommendations, is 30 milligrams per square decimeter of the total surface area of the glove for the year after adoption, 20 milligrams for the following year, and 15 milligrams thereafter. The powder limit approved for the three examination glove standards (D3578, D5250, and D6319) is 20 milligrams per square decimeter of the total surface area of the glove for the year after adoption, 15 milligrams for the following year, and 10 milligrams thereafter.

First, as described above with respect to protein, the amount of powder on gloves depends on the surface area of the glove and differs significantly for different sizes of gloves. Indeed, the ASTM Task Group initially considered and rejected the concept that the recommended limit on powder be stated on a per glove basis and decided that it should be expressed in milligrams of powder per square decimeter in any standards promulgated by ASTM.

Second, given the significant differences between surgeon's gloves and patient examination gloves, the same per glove powder limit would be unreasonable. Surgeon's gloves differ from examination gloves in that (I) they are designed separately to fit each hand with opposable thumbs, (ii) they are longer and differ in thickness from examination gloves, and (iii) they usually are sized to the half size rather than merely small, medium, and large, as are examination gloves. Based on these factors, surgeon's gloves clearly are designed to fit more snugly to the hand than examination gloves. This closer fit is necessary to provide better "feel" to the user for the delicate finger manipulations required in surgery.

Because they usually are longer and fit more snugly than examination gloves, surgeon's gloves require much more powder for donning than do examination gloves. In addition, surgeon's gloves are often donned while the hands are still wet, which requires more powder to permit donning than if the hands are dry. All of these circumstances make the amount of powder needed for surgeon's gloves significantly greater than for examination gloves.

## III. While HIMA Supports Certain Changes in the Labeling of Medical Gloves, FDA's Proposed Changes Lack a Scientific Basis and Would Unnecessarily Burden Industry.

The proposed rule includes new labeling requirements which, if adopted, would require the re-labeling of virtually all surgeon's gloves and patient examination gloves. FDA proposes to require latex gloves to carry not only the "caution" statement already required by 21 C.F.R. § 801.437 of the agency's regulations but also additional statements containing an FDA "recommendation" as to maximum levels of protein and powder per glove and a declaration of the amount of powder and protein contained in that particular product. In addition, the proposal would require for the first time that powdered synthetic (non-latex) gloves contain a Section 801.437 "caution" statement, an FDA recommendation as to the maximum amount of powder per glove, and a declaration of the amount of powder in that particular product. HIMA opposes almost every element of these new labeling requirements, for the reasons set forth below, and proposes alternative labeling that it believes would better inform the user as to the relevant characteristics of these products.

Initially, HIMA notes that the medical glove industry has just recently completed re-labeling of all latex gloves with the "caution" statement required by Section 801.437, which was intended to address the same basic safety concerns as the new proposed labeling. Without some significant new scientific information not available when the earlier rule was promulgated, it is difficult for the

agency to justify requiring another, even more extensive, re-labeling of these products for essentially the same purpose. HIMA is not aware of any such new information and considers it unreasonable under the circumstances for the agency to propose such extensive re-labeling. HIMA does, however, support some changes in the labeling of both powdered and powder-free latex gloves as described below.

### A. FDA "Recommendations"

One of the basic elements of the labeling proposal is that almost all medical gloves must contain an FDA "recommendation" as to the maximum amount of protein and/or powder per glove.[5] HIMA opposes FDA making any such recommendations for two reasons.

First, an FDA "recommendation" implies to the user that there is a scientific basis for that recommendation and that the user would benefit from following FDA's recommendation. However, as noted above, FDA acknowledges in the preamble to the proposal that "no systematic epidemiological data exist to identify the risk of airborne NL protein allergens." 64 Fed. Reg. 41,717. This confirms HIMA's view that there is insufficient scientific evidence to support a determination of a particular level of either powder or protein below which the risk of allergic reaction is significantly less. As such, any FDA recommendation as to the maximum amount of protein and/or powder per glove appears squarely inconsistent with Section 201(n) of the Federal Food, Drug, and Cosmetic Act in that any recommendation would fail to reveal the material fact that it is not based on scientific data.

Second, the "FDA recommends..." language is appropriate only for use in the United States and might not be acceptable in many foreign countries. This could necessitate separate labels for the United States and the rest of the world, and could significantly increase the costs of the products involved.

### B. Protein and Powder Levels for Gloves

HIMA opposes the proposed requirement that the labels for latex gloves contain a statement of the actual amount of protein and powder per glove. Not only is this proposal unreasonable because it requires the statement be made on a per glove basis[6], but also because it would require gloves to be labeled with different amounts, based on the test results relating to those particular

---

[5] As discussed extensively in other portions of these comments, even if, contrary to HIMA's position, FDA were to make "recommendations," those "recommendations" should be expressed on a per unit area basis, as are ASTM's recommended limits for protein and powder, rather than on a per glove basis.

[6] See Section II above.

gloves. This would lead to some gloves being labeled as having a few more or less micrograms of protein or milligrams of powder than other gloves when the differences in amount may be both insignificant and possibly wrong, because of the imprecision and lack of reproducibility of the approved test methods. Thus, users would be misled into thinking that the gloves with the lower declared protein or powder value were more desirable, when this may not be the case.

HIMA proposes instead that, with respect to protein content declarations, FDA adopt a three tier-system: First, gloves meeting the protein level of 50 micrograms or less per square decimeter should be allowed to declare: "Contains $50\mu g/dm^2$ or less protein," which is similar to what FDA presently allows based on premarket notification (510(k)) clearances. HIMA assumes that products holding such 510(k)s would be permitted to convert their present approved labeling to this declaration (assuming this would entail merely a wording change, and not a substantive modification). HIMA further assumes that, if this regulation is promulgated, low protein declarations will be allowed without a requirement for 510(k) clearance based on the manufacturer having substantiating data in its files. Second, gloves meeting the protein level of 200 micrograms or less per square decimeter would be required to declare "Meets ASTM Standard D-XXXX." Finally, gloves not meeting this standard would be required to declare "Does not meet ASTM Standard D-XXXX for protein."

With regard to powder content declarations, HIMA proposes that FDA adopt a two-tier system: Gloves meeting the relevant ASTM mg per unit area powder limit would be required to declare "Meets ASTM Standard D-XXXX." Gloves not meeting this standard would be required to declare "Does not meet ASTM Standard D-XXXX for powder."

### C. Labeling for Powdered Synthetic Gloves

FDA proposes that powdered synthetic (non-latex) gloves, both surgeon's gloves and patient examination gloves, be labeled with the statement:

"Caution: Glove powder is associated with adverse reactions."

In HIMA's view, there is insufficient evidence to support requiring this statement on synthetic examination gloves. Indeed, HIMA believes that reports relative to examination gloves -- concerning glove powder alone, not associated with latex allergens -- are very sparse and do not suggest sufficient potential for harm to justify this statement. In addition, HIMA notes that FDA's proposed caution statement arguably would be unnecessary for surgeon's gloves, given that the agency already requires powdered surgical gloves to carry a caution statement.[7]

---

[7] See FDA's PMA Guidance for Glove Dusting Powder (requiring surgical gloves treated with dusting powder to be labeled with the statement, "Caution: After donning, remove powder by wiping gloves thoroughly with a sterile, wet sponge, sterile wet towel, or other effective method.")

In addition, for the reasons expressed above with respect to latex gloves, HIMA opposes FDA's proposal that the label on powdered synthetic gloves contain an FDA "recommendation" as to maximum powder content and declare the glove's actual powder content. Again, there is no scientific basis for FDA to "recommend" any particular level of powder. Instead, as described above with respect to powdered latex gloves, HIMA recommends that FDA adopt a two-tier system for powder content declarations. Gloves meeting the relevant ASTM mg per unit area powder limit would be required to declare "Meets ASTM Standard D-XXXX." Gloves not meeting this standard would be required to declare "Does not meet ASTM Standard D-XXXX for powder."

## IV. FDA Should Clarify that Manufacturers are Permitted to Rely on Currently Established Accelerated Aging Stability Protocols to Determine Expiration Dating, Until Such Time as an ASTM or FDA Protocol is Finalized, and Manufacturers Have Had Sufficient Time to Utilize Such Protocol.

Under the proposed rule, expiration dating would be based on "adequate stability studies demonstrating the physical and mechanical integrity of the gloves over their labeled shelf life from the date of manufacture." See Proposed 21 C.F.R. § 801.440(d)(3). In the preamble to the proposed rule, FDA states that expiration date testing would have to be conducted "according to a validated stability study protocol to determine the shelf-life of the gloves." 64 Fed. Reg. 41,715 (emphasis added). The agency further states that it has been "unable . . . to determine whether any validated stability study protocols exist employing accelerated aging methodologies." 64 Fed. Reg. 41,716. FDA specifically solicits comments on the "availability of accelerated aging stability study protocols which are predictive of glove shelf-life." Id.

FDA's proposal would require expiration dating to be placed on the labeling of all medical gloves. HIMA supports the general principle of requiring expiration dating on medical gloves. However, it is HIMA's understanding that a validated accelerated aging stability study protocol does not currently exist, but that ASTM is in the process of developing such a protocol, and that FDA has recently issued a draft guidance document containing recommended protocols. See Draft Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves, November 16, 1999. Therefore, HIMA respectfully requests that manufacturers be permitted to rely on data from existing accelerated aging study protocols until ASTM or FDA finalizes a validated protocol, and manufacturers have had sufficient time to develop data based on such protocol. Indeed, given that ASTM is in the process of developing a validated protocol, and FDA has already issued draft guidance containing a recommended protocol, it would be unnecessarily burdensome to require manufacturers to independently develop their own validated protocols.

## V. In Establishing an Implementation Timeframe, FDA Should Consider the Significant Steps Industry Already has Taken to Address the Agency's Concerns, the Time Realistically Needed to Make Labeling Changes, and the External Uncertainties that Could Prolong the Implementation Process.

FDA specifically requested comments on the implementation timeframe for the proposed rule. HIMA believes there are a number of issues the agency should consider in developing an appropriate implementation timeframe.

As an initial matter, HIMA urges FDA to take note of the significant steps that manufacturers have already taken to address the agency's concerns about medical gloves. As one important example, ASTM has worked swiftly to develop protein and powder standards, which the vast majority of glove manufacturers now are implementing.

Second, in HIMA's view, the implementation timeframe should reflect a realistic assessment of the time needed to make required label and process changes. For example, HIMA estimates that the labeling changes contained in the proposed rule would take at least two years to implement. Thus, HIMA supports FDA's proposed two-year implementation timeframe. See 64 Fed. Reg. 41,716.

Finally, HIMA notes that certain external uncertainties potentially could prolong the timeframe needed to implement the proposed rule. For example, as discussed in Section IV, a validated protocol for determining shelf-life does not appear to currently exist. Thus, as a practical matter, industry compliance with FDA's expiration dating requirements through use of validated protocols should not be required until ASTM or FDA finalizes a validated protocol, and manufacturers have had sufficient time to develop data based on such protocol.

## VI. Responses to FDA's Specific Questions

In the proposed rule, FDA requests comments on 12 specific issues. HIMA's response to these 12 questions is given below:

*Question 1 -- Implementation timeframe.* HIMA's comments regarding implementation timeframe are in Section V above.

*Question 2 -- Recommended powder limit.* HIMA's comments on FDA's recommended powder limit are in Section II above. With regard to FDA's specific question concerning minimum powder levels, HIMA notes that ASTM has not determined a minimum level of powder that is needed for adequate donning of latex gloves. In HIMA's view, such a level would be difficult to determine

because the minimum level of powder needed for adequate donning is heavily dependent upon the design and formulation of the particular glove in question.

*Question 3 -- Additional labeling for primary ingredients in glove powder.* In HIMA's view, it is neither feasible nor desirable to include additional labeling with respect to the "primary ingredients" in glove powder. Glove powder for surgeon's gloves is a Class III medical device subject to agency premarket approval. See 21 C.F.R. § 878.4480. There is no added benefit to the glove user from having the product label expanded to include the ingredients of glove powder, since any potential health risk to date is associated with glove powder generally, and not with a specific ingredient.

*Question 4 -- Powder level for powder-free gloves.* HIMA objects to FDA's recommended limit of no more than 2 mg of powder per glove for powder-free gloves to the extent that it is inconsistent with ASTM limits. By adopting the ASTM approach, which steps down the allowable limit from 4 mg per glove to 2 mg per glove over 2 years, FDA would be consistent with the established industry trend toward achieving the 2 mg limit.

*Question 5 -- Potential future requirement that all gloves be powder-free.* HIMA strongly objects to any future requirement that all gloves marketed in the United States be powder-free. Indeed, certain health care professionals prefer using powdered gloves, and, furthermore, as described in Section I above, there is conflicting scientific evidence regarding the claim that powdered latex gloves cause adverse health effects. Moreover, some powdered gloves may provide certain benefits as compared to some powder-free gloves, including increased strength, perspiration absorption, and greater tactile properties. Therefore, requiring that all gloves be powder-free would not be in the public's interest.

*Question 6 -- Potential restrictions on the sale (advertising), distribution, and use of powdered medical gloves.* As described in Section I above, HIMA questions the scientific basis of FDA's assessment of the risk associated with powdered gloves. In addition, as noted in the response to Question 5 above, some powdered gloves may provide certain benefits to users as compared to some powder-free gloves. HIMA views the proposed rule (with HIMA's recommended changes), in conjunction with existing requirements, as more than adequate to control the sale (advertising), distribution, and use of powdered latex gloves. Thus, HIMA strongly objects to any additional such restrictions.

*Question 7 -- Recommended protein limit.* HIMA's comments on FDA's recommended protein limit are in Section II above.

*Question 8 -- Feasible alternative approaches to achieve FDA's objectives.* HIMA urges FDA to allow sufficient flexibility in its proposed rule to accommodate the use of other future valid scientific approaches in order to achieve its objectives of reducing adverse health effects from allergic reactions and foreign body reactions by controlling the levels of water-extractable protein and glove powder in NL gloves. Indeed, in HIMA's view, failure to build in such flexibility could pose impediments to achievement of FDA's objectives. For example, ASTM, with FDA support, recently

*Question 9 -- Recommended versus required powder and protein limits.* As noted above, FDA acknowledges that "no systematic data exist to identify the risk of airborne NL protein allergens." 64 Fed. Reg. 41,717. Given this lack of scientific data, HIMA believes that any limits on powder and protein should be recommended, as the proposed rule contemplates, rather than required limits. As discussed above, HIMA strongly urges FDA to avoid arbitrary recommendations, and, instead, base its actions on ASTM consensus standards with respect to protein and powder limits.

*Question 10 -- Shelf-life.* HIMA's comments on shelf-life and accelerated aging stability study protocols are in Section IV above.

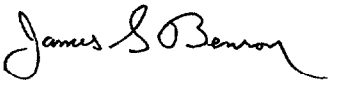
*Question 11 -- Special handling systems for facilities using powdered medical gloves with over 120 mg of powder per glove.* HIMA strongly opposes a requirement that special air handling systems be installed in facilities using medical gloves with over 120 mg of powder per glove. In HIMA's view, given the expense and inconvenience associated with installing special handling systems, imposing such a requirement would amount to a de facto ban on powdered latex gloves. Moreover, HIMA believes that such a requirement would be unjustified, given the questionable scientific basis underlying FDA's assessment of the risk associated with medical gloves. See Section I above.

*Question 12 -- Whether exemptions or variances should be permitted.* It is HIMA's strong view that, as long as they are adequately justified, exemptions and/or variances from labeling requirements or restrictions on distribution or use of medical gloves should be permitted.

* * *

HIMA 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,



James S. Benson
Executive Vice President
Technology and Regulatory Affairs