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June 12, 2003

Document Management Branch
Food and Drug Administration
5630 Fishers Lane - Rm. 1061 – (HFA-305)
Rockville, MD 20852

Re: Docket No. 03D-0137, CDRH 200317
Medical Devices: Draft Guidance for Industry and FDA;
Surgical Masks – Premarket Notification Submissions

Dear Sir:

Cardinal Health, Medical Products and Services (Cardinal) appreciates the opportunity to comment on the Draft Guidance, currently under review, for Surgical Masks. Our comments are as follows:

Section 6. **Risks to Health**

Comment: Cardinal recommends that in the table located at line 195, the word "bacterial" be eliminated from the second box under "Identified Risk". The box would then read as follows: "Inadequate Filtration Efficiency". We believe that both Particulate and Bacterial filtration efficiencies are important variables to consider when evaluating health risks.

Section 7. **Fluid Resistance**

Comment: The Section as presently written mandates that all Masks meet the requirements necessary to substantiate a Fluid Resistance claim. Cardinal is of the opinion that there are occasions within medical practice which warrant the use of a Mask but not necessarily one which has fluid resistance properties at the levels identified in the draft guidance, i.e., a horizontal velocity stream generated by 80 mm Hg or greater. Additionally, there are Masks marketed today that are not able to meet a fluid resistance claim at the minimum velocity identified. The use of a fluid resistance claim should be an option available to the manufacturer as is the ability to make an "impervious" claim for Gowns and Drapes. Examples of Masks not requiring a fluid resistance claim are:
Isolation Masks, Neonatal Masks, Masks used in Dental Offices, Masks used to transport patients, Masks used in the ICU, etc.

In order to accommodate this recommendation it may be necessary for the Agency to create another 21 CFR reference for "Non Surgical Masks" and only include "Surgical Masks" in 21 CFR 878.4040.

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Section 8. **Filtration Efficiency**

Comment: Cardinal recommends that the "Modified Greene and Vesley Method: Method for evaluation of bacterial filtration efficiency of surgical masks. J Bacteriol 83:663-667. (1962)", identified at line 241 of the document, be deleted as a recommended test method due to the inability of the test to produce consistent test results. Our experience with this test method has produced artificially high results as compared to the other methods listed.

We recommend that the subtitle "Filter Efficiency Performance", line 226, be changed to "Particulate Filtration Efficiency". We believe this to be a more commonly used term and also to attain conformity to other Sections of the document.

We recommend that the identification of the draft standard "FXXXX, Determining the initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres (Second Draft)" be added to end of line 230 as a recommended testing method.

Section 9.**Differential Pressure (Delta-P) Test**

Comment: We recommend the elimination of "either of" on line 254 and the use of the singular "standard" on line 254 since only one standard is identified as a recommended testing method, i.e., line 256, "Mil-M-36945C 4.4.1.1.1 Method 1 Military Specifications: Surgical Mask, disposable (June12, 1975)".

We recommend eliminating the use of the table identified at line 261, "Comfort Scale used in Delta-P testing". The recommended test method identified at line 256 and also stated above does not use adjectives to report test results. Adjectives such as those used in the second half of the table, located at line 261, are highly subjective and will only lead to misconception.

Section 10. **Flammability Testing**

Comment: Cardinal recommends eliminating the identification of "NFPA Standard #702-1980: Standard for the use of inhalation anesthetics", line 268, from the guidance under consideration. As the Agency properly notes in the footnote at the bottom of page #8 of the document, the standard identified at line 268 is not an active standard. It is not even a draft standard; it is an obsolete standard. Therefore, it has no standing as a valid candidate for inclusion in a guidance document currently under review. Including such an obsolete standard will only cause confusion for both Premarket Notification sponsors and Healthcare Professionals who use the marketed product.

Eliminating the NFPA standard, line 268, will necessitate the deletion of "Class 2" from line 275 changing it to read as follows: "We recommend that Class 1 flammability materials be used in surgical masks intended for use in the Operating Room." Additionally changing "Class 4" to "Class 3" on line 278. We recommend that the first sentence of line 278 read as follows: "FDA believes that devices with a Class 3 rating, per 16 CFR 1610, are not appropriate for use in the Operating Room."

Section 11. **Labeling**

Comment: Cardinal recommends that since only Class 1 materials are appropriate for use in the Operating Room, any Warnings associated with the use of Class 3 materials are unnecessary and should be deleted from the guidance under consideration, i.e., lines 296 through 304.

As mentioned previously, Cardinal recommends that the Agency consider a separate 21 CFR reference for "Non Surgical Masks". This would create a situation similar to that enjoyed by Surgeon and Exam Gloves, a situation in which more specific identifications can be made.

Appendix II. **Summary Report Sample Formats**

Comment: Cardinal recommends that at line 315, the box identified as "Filter Efficiency Performance" be changed to "Particulate Filtration Efficiency". As stated previously, we believe this to be a more accepted term.

Additionally, results reported in the "Particulate Filtration Efficiency" box should be as a % and not in microns.

Please feel free to contact me at 847-785-3310 or at the above address, if there are any questions concerning our comments or if clarification is required.

Sincerely,

Joseph A. Mertis

Joseph A. Mertis
Director, Regulatory Affairs