

17-April-2004

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA – 305)
Rockville, MD 20852

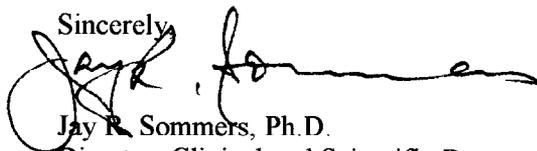
RE: Docket No. 03D-0137

Dear Division of Dockets Management:

I am enclosing some comments regarding Docket No. 03D-0137: “Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submissions.”

It is our intention, that these comments will clarify, improve, and remove any ambiguity from this guidance document. Please let me know if you would to discuss this submission in greater detail. Thank you.

Sincerely,



Jay R. Sommers, Ph.D.
Director, Clinical and Scientific Documentation
Health Care

2003D - 0137

CS

DOCKET NO. 03D – 0137

**“Guidance for Industry and FDA Staff:
Surgical Masks – Premarket Notification [510(k)]
Submissions”**

**Comments from Kimberly- Clark Corporation
April 17, 2004**

- 1. Replace the adjective for masks, i.e., “surgical,” in the title and throughout the document to “medical,” except where noted. Although other types of masks are described in Section 1. Introduction, e.g., isolation masks, procedure masks, and dental masks, they are not surgical masks. Keeping “Surgical Masks” in the title will mislead people looking for information about these other types of masks.**
- 2. Remove the identification of the year for all referenced standards, e.g.,
 - a. p. 8 – ASTM F 1215, not ASTM F 1215 - 89
 - b. p. 9 – ASTM F 2101, not ASTM F 2101 - 01
 - c. p. 10 – NFPA Standard 702, not NFPA Standard 702 – 1980**
- 3. Section 8. Filtration Efficiency: p. 9 – Bacterial Filtration Efficiency:
 - a. Remove the first method – Mil Standard M369454C. This method has been converted to ASTM F 2101.
 - b. Remove the second method – Modified Greene and Vesley Method. This method is not as rigorous as ASTM F 2101 and gives the user a “false sense of security.”**
- 4. Section 9. Differential Pressure (Delta – P) Test: p. 10 – Comfort Scale Used in Delta –P Testing (p. 10):
Remove this table. Comfort and heat are not directly related to Delta – P and do not take into account humidity, test conditions, and other factors. Additionally, comfort is a subjective term and can not be quantified using this table.**
- 5. Section 10. Flammability Testing: p. 10 -
 - a. Remove UL 2154. This test method is titled “ Fire Tests of Surgical Fabrics” and is not designed, nor is it applicable for face masks.
 - b. Reword the sentence: “We recommend that Class 1 and Class 2 ...” to: “Medical masks must meet Class 1 CPSC CS – 191 – 53. We recommend that surgical masks meet either Class 1 or Class 2 NFPA 702 flammability for intended use in the operating room.”**

6. Labeling – Warning; p. 11 -

Clarify the wording of this section as follows:

a. For a medical mask that does not meet the Class 1 minimum performance rating of CPSC CS 191 – 53; it must be labeled:

“This device does not meet the minimum flammability standards as defined by the Consumer Product Safety Commission (CPSC).”

b. For a surgical mask that that is rated Class 3 by NFPA 702; it should be labeled:

“This device may ignite and burn when used in the presence of high energy ignition sources (e.g., cauteries, lasers, fiberoptic devices, etc.) or flammable gases.”

7. Appendix II. Summary Report Sample Formats; p. 13 -

For surgical masks that are not NIOSH certified:

Under Performance Characteristics, the 5th property – Flammability Class;

Remove “Class 1.”