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January 12, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
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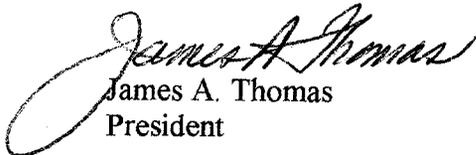
To Whom It May Concern:

We are writing in response to a notice in the Federal Register of Friday, July 30, 1999 regarding a Proposed Rule to Reclassify Surgeon's and Patient Examination Gloves.

Members of ASTM Committee D11 on Rubber have carefully reviewed the proposed rule and provide the comments on the attached letter.

Thank you for the opportunity to comment.

Sincerely,


James A. Thomas
President

CC: D11 Executive Committee
D11.40 Subcommittee

98N-0313

C46



100 Barr Harbor Drive ■ West Conshohocken, PA 19428-2959

Telephone: 610-832-9500 ■ Fax: 610-832-9555 ■ e-mail: service@astm.org ■ Website: www.astm.org

Committee D11 on RUBBER

Chairman: ALEK VARE, Michelin/QA/SQA at Mar 55 Michelin Rd, Box 197, Greenville, SC 29602-1987, (864) 422-4469, FAX: 864-422-3505
First Vice Chairman: CLAIR R. HARMON, Cooper Tire & Rubber Co, Lima & Western Ave, Findlay, OH 45840, (419) 424-4338, FAX: 419-420-6006, EMail: crharmon@coopertire.com
Second Vice Chairman: ROBERT C. MOYER, Bridgestone/Firestone Inc, Material Sciences Group, 1200 Firestone Pkwy, Akron, OH 44317-0001, (330) 379-6679, FAX: 330-379-6935, EMail: roberto164@bfs.e-mail.com
Secretary: FRANK E. LUSSIER, Uniroyal Chemical Co, Benson Rd, Middlebury, CT 06749, (203) 573-3196, FAX: 203-573-3105
Membership Secretary: THOMAS S. LIOTTA, Continental General Tire Inc, 1950 Continental Blvd, Charlotte, NC 28273, (704) 583-8672, FAX: 704-583-3996, EMail: tliotta@gentire.com
Staff Manager: TIMOTHY S. BROOKE, (610) 832-9729, EMail: tbrooke@astm.org

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Subject: Surgeon's and Patient Examination Gloves; Reclassification
21 CFR Parts 801, 878, and 880
Docket Number 98N - 0313
RIN 0910 - AB74

ASTM is a not-for-profit organization that provides a forum for producers, users, ultimate consumers, and representatives from government and academia to meet on common ground and write consensus standards for materials, products, systems, and services.

The 120 milligram per glove powder limit proposed by the FDA would be applicable to all medical gloves, regardless of size. A simple per glove limit of this kind was considered and rejected by the ASTM Maximum Powder Working Group as unreasonable in light of the differing amounts of powder on gloves of different sizes and the differing amounts required for surgeon's gloves and patient examination gloves due to the difference in design and use.

The amount of powder on gloves depends on the surface area of the gloves and differs significantly for different glove sizes. Because of this, the ASTM Working Group rejected the concept that the recommended limit on powder be stated on a per glove basis. It decided that it should be expressed in milligrams of powder per square decimeter. ASTM has approved a powder limitation per square decimeter for powdered gloves for three-FDA recognized consensus standards: D3577, D3578, and D5250 for rubber surgical gloves, rubber examination gloves and polyvinyl chloride medical gloves respectively and also the ASTM standard for nitrile examination gloves, D6319. These revised standards, including powder limits, will be published in the first quarter of 2000.

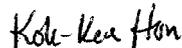
The powder limit approved for the surgical glove standard, based on the Working Group recommendations, is 30 milligrams per square decimeter of the total surface area of the glove for the year from the date the standard was first published and 15 milligrams thereafter. The powder limit approved for the three examination glove

standards is 20 milligrams per square decimeter of the total surface area of the glove for the year from the date the standard was first published, 15 milligrams for the following year and 10 milligrams thereafter. Each of these limitations takes into account the differences in glove size, because they are based on total surface area of the glove, and also considers the ability of glove manufacturers to adjust their operations to meet these limitations. ASTM therefore recommends that the FDA adopt these limits in place of its proposed 120 milligram limit.

ASTM's powder limits recognize the need to consider the differing amounts of powder necessary for the surgeon's gloves and patient examination gloves. This is based on the very significant differences in design between these two devices. Surgeon's gloves differ from examination gloves in that they are designed to fit each hand with opposable thumbs. They are also longer and differ in thickness from examination gloves. In addition, they are usually 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 surgeon's gloves are longer and have a tighter fit, there is a much greater need for powder to allow the donning and removal of them than for examination gloves. Furthermore, surgeon's gloves are often donned while the hands are still wet, which requires more powder to facilitate 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. Setting a single limit for both types of gloves thus will inevitably result in either more powder or not enough powder being permitted for reasonably easy use of surgeon's gloves.

Thank you for the opportunity to comment.

Sincerely,



Kok-Kee Hon
D11.40 Chairman



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