

American
Dental
Association



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

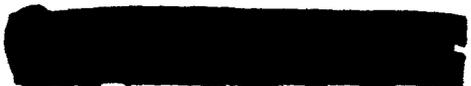
RE: Comments concerning the Food and Drug Administration's (FDA) proposed rule on *Medical Devices; Patient Examination and Surgeons' Gloves; Test Procedures and Acceptance Criteria*, 68 Fed. Reg. 15404-15417.

Dear Sir/Madam:

The American Dental Association (ADA) is pleased to provide the FDA with comments regarding the proposed rule: *Medical Devices, Patient Examination and Surgeons' Gloves; Test Procedures and Acceptance Criteria*. The ADA represents over 147,000 dentists in the United States and seeks to advance the art and science of dentistry, promoting high quality dental care and the oral health of the American public.

The ADA has substantial experience and expertise involving standards for patient examination gloves. Patient examination gloves are the type of glove used for most dental procedures as part of dentists' overall adherence to infection control protocols. As the ANSI-accredited standard development organization for dental products, the ADA has led the development of consensus standards for patient examination gloves made of natural rubber latex (ANSI/ADA Specification No.76); nitrile (ANSI/ADA Specification No.102) and vinyl (ANSI/ADA Specification No.103). In the process, the Association has worked closely with other standards organizations, such as the International Organization for Standardization (ISO) and American Society for Testing Materials (ASTM).

The Association supports the proposed FDA rule. It is consistent with the Association's efforts to improve the quality of products used in the practice of dentistry and should provide even better protection for dentists and the patients they serve by enhancing the barrier quality of medical gloves available to them. In particular, the proposed changes affecting patient examination gloves will promote harmonization with the ANSI/ADA Specifications cited above, as well as the consensus standards of ISO and ASTM.


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The ADA appreciates the FDA's consideration of our comments and would welcome the opportunity to work with the FDA on this issue. Should you have any questions, please contact Jonathan B. McLeod, Manager, Legislative and Regulatory Policy at (202) 789-5176.

Sincerely,

Handwritten signature of T. Howard Jones, D.M.D. in black ink.

T. Howard Jones, D.M.D.
President

Handwritten signature of James B. Bramson, D.D.S. in black ink.

James B. Bramson, D.D.S.
Executive Director

THJ:JBB