

May 13, 2015

Dr. Jeffrey Shuren
Director, Center for Devices and Radiological Health
WO-66-5542
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, Maryland, 20993-0002

Dear Dr. Shuren:

The American Dental Association (ADA) is the nation's oldest and largest professional association for dentistry and is committed to improving the oral health of the public. As a patient-centered, scientifically-based and ethically-driven association with over 158,000 members, the ADA takes seriously the safety of all dental patients. Fundamental to patient safety is the regulation of dental materials, equipment and supplies by the Food and Drug Administration (FDA), ensuring that all such items meet FDA standards and preventing their unauthorized purchase.

This letter respectfully requests that the FDA review and aggressively enforce policies and procedures governing the purchase of dental equipment, materials and supplies to ensure these sales are restricted to licensed dentists or dental practices registered by the state and that the items sold meet FDA standards. The ADA is increasingly concerned that individuals who are not properly licensed to practice dentistry are purchasing dental equipment, frequently from grey market suppliers, for the illegal practice of dentistry contrary to the FDA's requirements.

The ADA is not suggesting this is a problem among reputable companies, such as eBay and Henry Schein, Inc., which have policies warning against unauthorized purchasing. For example, such sellers when listing medical devices that require government authorization to distribute to third parties include the following text: "The sale of this item may be subject to regulation by the U.S. Food and Drug Administration and state and local regulatory agencies. If so, do not bid on this item unless you are an authorized purchaser. If the item is subject to FDA regulation, I will verify your status as an authorized purchaser of this item before shipping of this item." You may also be interested in a video presentation prepared by Patterson Dental on the issue of grey market and black market dental equipment, materials and supplies: <http://dentalsupplyintegrity.com/>. As stated above, the ADA's primary concern is with grey market sales of dental equipment occurring outside established distribution chains.

The ADA looks forward to working with the FDA on the matters addressed in this letter. Dr. Frank Kyle in the ADA's Government and Public Affairs Division at 202-789-5175 or kylef@ada.org will follow-up with your office.

Sincerely,

Maxine Feinberg, D.D.S.
President

Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director and Chief Operating Officer

Cc: Dr. Markham Luke, Medical Officer, Office of Device Evaluation
Ms. Jan Welch, Office of Compliance/ CDRH, Acting Director
Dr. Susan Runner, Branch Chief Dental Devices, CDRH/FDA/ODE