

October 13, 2006

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

Dear Sirs:

The Dental Trade Alliance (an association comprised of 220 members) represents manufacturers, distributors and laboratories providing medical devices to the dental industry, including many of the largest and smaller manufacturers. Since unification of the highly respected Dental Manufacturers of America and American Dental Trade Associations, DTA members have been involved in all aspects of dental including manufacturing, distribution, export, import and international commerce. The public's overall oral health and patient safety are priorities for all DTA member companies.

DTA applauds FDA for promoting public health care and encouraging full disclosure of medical devices. Yet in practical terms, most all dental products (medical devices) offer minimal health risks to patients. Because dental type medical devices offer little risk to the public, the dental trade agrees new regulations for identification of medical devices should be instituted in a way that is practical, flexible and not burdensome to small companies. The DTA position refers to the following points:

- DTA does not believe Unique Device Identifiers will prove particularly practical for dental offices and their patients.
- Time is a factor in implementing UDI requirements. DTA believes a five-year period is the minimum time required for manufacturers to implement new regulations. Five years provides flexibility without undue hardships for the industry.
- Neither the use nor the format of Unique Device Identifiers should be mandatory except where their absence would result in a major health care risk.
- UDI should be based on existing standards which are well integrated into the market place and meet the basic requirements.
- UDI will add cost, and may be onerous for small manufacturers, distributors, and users; a general information campaign will be required if UDIs are widely adopted, particularly geared towards the general public.
- Data elements required should be limited to Manufacturer #, product #, lot # and expiration when necessary.

- UDI's should be only required on the sales packing unit except for large hardware equipment.
- Government efforts to require UDIs should include Centers for Medicare and Medicaid Services, Department of Defense, and others,
- Any development of a UDI requirement should be closely aligned with International programs and requirements,

DTA strongly urges your agency to consider these important criteria when implementing new procedures for identification of medical devices.

Sincerely,

Gary Price
CEO
Dental Trade Alliance

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