C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

1928 '03 SEP 22 P4:19

September 22, 2003

E. EDWARD KAVANAUGH
PRESIDENT

Dockets Management Branch(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Draft Guidance for Industry and FDA Staff; Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002 – Identification of Manufacturer of Medical Devices

Dear Sir or Madam:

In accordance with the Notice published in 68 Fed. Reg. 37161 (June 23, 2003), The Cosmetic, Toiletry, and Fragrance Association ("CTFA") hereby submits the following comments with respect to the draft guidance for industry and FDA staff entitled "Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002 – Identification of Manufacturer of Medical Devices."

CTFA represents the cosmetic, toiletry, and fragrance industry.[1] Although devices are not part of CTFA's normal constituency, we are filing these comments on behalf of our member companies that manufacture and/or distribute medical devices used in association with personal care products, *e.g.*, toothbrushes, insoles, and bandages.[2]

CTFA believes that the current labeling requirements specified in 21 CFR 801.1 are sufficient to track medical devices in order to identify the manufacturer and/or distributor when necessary. The requirement to identify the manufacturer on each

---

[1] CTFA is the national trade association representing the cosmetic, toiletry and fragrance industry. The products manufactured by CTFA members include products such as color cosmetics, skin care products, sunscreens, oral care products, antiperspirants, deodorants and fragrances. CTFA has not represented, nor has it been asked to represent, the medical device industry, and that industry will presumably file its own comments addressing the draft guidance. Founded in 1894, CTFA has almost 600 members, approximately one-half of which manufacture or distribute such products throughout the United States. Other CTFA members supply good and services to those manufacturers and distributors.

[2] The 1935 Senate Report on the legislation that ultimately became the Federal Food, Drug, and Cosmetic Act states that "the definition of the term cosmetic does not include devices." S. Rep. No. 361, 74th Cong., 1st Sess. 3 (1935).

03D-0226 C3

1101 17TH ST., N.W., SUITE 300 WASHINGTON, D.C. 20036-4702
202.331.1770 FAX 202.331.1969
http://www.ctfa.org
SECURING THE INDUSTRY'S FUTURE SINCE 1894

device is inappropriate and unnecessarily burdensome for the type of medical devices used in the context of personal care and hygiene.

Strict interpretation of the term "manufacturer" could require the name of a party who is not the actual responsible party to be attached to the device, thereby creating unnecessary confusion and potential confidentiality issues with respect to contract manufacturers and private label distributors. For example, an American company may act as a distributor for a foreign manufacturing company that is unknown to American consumers. This guidance would require the device to identify the foreign company - information that would not be useful to an American consumer and which offers no practical recourse in the event of a problem with the product. Consumers would not benefit from knowing the manufacturer of a medical device and may in fact be confused as to who they should contact in case of a question or adverse event.

Furthermore, the requirement to label with the name of the actual manufacturer would disrupt established supply and distributor relationships. Distributors often work with overseas manufacturers. Imposition of new labeling requirements to identify the names of new and/or different manufacturers under tight shipment deadlines is unnecessarily burdensome. Existing regulations are adequate and substantive enough to address the Agency's concern for accountability and traceability.

For these reasons, CTFA requests that FDA exercise its discretion not to enforce this requirement for exempt and Class I medical devices. FDA has enforcement discretion and can conclude to take or not take action.[3] See also Section 309 of the FD&C Act. Enforcement and application of Section 301 to all medical devices, most *especially* exempt and Class I category devices that our members sell in association with personal care use, would provide no additional public health benefit. Existing regulations are adequate to address the needs of the Agency, industry and the public at large.

Respectfully submitted,

Thomas J. Donegan, Jr.
Vice President - Legal & General Counsel

[3] Heckler v. Chaney, 470 U.S. 821 (1985).