COLGATE-PALMOLIVE COMPANY

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5360 Fishers Lane, rm.1061
Rockville, MD 20852

Re: Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002 - Identification of Manufacturer of Medical Devices.
Docket No. 03D-0226

Dear Sir/Madam,

Colgate-Palmolive Company submits these comments to docket 03D-0226: Draft Guidance for Industry and FDA Staff: Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002 - Identification of Manufacturer of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.

As stated by previous comments to docket 02N-0534 (MDUFMA 2002) it appears that the original intent of Congress was to apply the labeling requirement in Section 301 only to reprocessed medical devices however this requirement was eventually expanded to include all medical devices. Therefore the Agency should exempt all medical devices except reprocessed devices from the requirements of Section 301 and narrow the focus of this guidance to include only reprocessed medical devices.

In addition the Colgate-Palmolive Company believes that the current labeling requirements specified in 21CFR 801.1 are sufficient to track medical devices in order to identify the responsible party when necessary and that the enforcement and application of Section 301 to all medical devices would provide no additional public health benefit. The requirement to identify the device manufacturer on each individual medical device is inappropriate and subjects the industry to unnecessary resource burden for the majority of medical devices.

The 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 creating unnecessary confusion and potential confidentiality issues with respect to contract manufacturers and private label distributors. For those devices

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requiring the identification of the responsible party directly on the device the party with ultimate responsibility would be preferred to the manufacturer.

The requirements of Section 301 would significantly increase the burden on industry by requiring the name of the original manufacturer on each device and increase the overall cost of medical devices in the healthcare system and potentially limit patient access to necessary medical devices.

In conclusion the Colgate-Palmolive Company feels that the requirement to label all medical devices with the manufacturers name is inappropriate and requests that the scope of this draft guidance be narrowed to include only those devices subject to reprocessing.

Respectfully,

Eugenie C Acosta

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