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

Re: Docket Number 02N-0534: Medical Device User Fee and Modernization Act (MDUFMA) of 2002

Dear Sir/Madam:

B. Braun Medical, Inc. is providing comments in response to the Federal Register Notice dated February 4, 2003 (See 68 F.R. at 5643) regarding Section 301 of MDUFMA.

Section 301 (a) of MDUFMA states:

> "If it is a device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, except that the Secretary may waive any requirement under this paragraph for the device if the Secretary determines that compliance with the requirement is not feasible for the device or would compromise the provision of reasonable assurance of the safety and effectiveness of the device."

B. Braun Medical, Inc. manufactures a large variety of single-use disposable medical devices and is a contract manufacturer for many medical device companies. Following a review of the history of the development of the above referenced section of the Act, it is B. Braun Medical Inc.'s belief that the original intent of this regulation was to apply to single-use devices that may be reprocessed. B. Braun Medical, Inc. urges the Agency to enforce section 301 of the Act only for reprocessed medical devices and grant exemption for all other medical devices. It does not appear that there is an added health benefit to place the original equipment manufacturer's name on medical devices. Additionally, there does not appear to be a problem with the current labeling requirements for medical devices. The current labeling requirements allow medical device users to identify the responsible party if needed.

B. Braun Medical Inc. is concerned that implementation of this section of the Act will require substantial changes to B. Braun Medical Inc.'s manufacturing operations and ultimately impact the design of B. Braun Medical Inc.'s products. To implement the identification of the manufacturer on all medical devices would require multiple manufacturing and design changes. Regardless of the method chosen to identify the manufacturer, the change will need to be identified, planned, conducted and validated. This will require normal production to be slowed

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or halted until the changes can be fully implemented. This process could have significant negative impacts on product availability and thus public health. All of the additional manufacturing and process changes required to implement Section 301 of the Act will lead to increased product costs in a time when there is a major effort to control medical spending.

Another consideration is the confusion that would be created by having a medical device marked with the B. Braun Medical Inc. name or symbol, but the product labeling marked with the party responsible for placing the medical device in commercial distribution. This situation puts B. Braun Medical Inc. at a significantly increased risk as B. Braun Medical Inc. has no control over the further processing or labeling of components manufactured by B. Braun Medical Inc. and purchased by other manufacturers. To have the B. Braun Medical Inc. name on a product that B. Braun Medical Inc. does not have control of the processing and labeling poses excessive risk to B. Braun Medical Inc.

If there is a literal implementation of this section of the Act, it is not feasible for many medical device companies to comply within the allotted eighteen months. The time needed to identify the processes to be changed, how to change them, testing that needs to be completed, validation that is required and the actual process of completing the activities listed will greatly exceed the eighteen month timeframe. Additionally, no guidance has been promulgated to address the concerns of manufacturers and provide a clear interpretation of the Agency's expectations. This lack of guidance and clear direction is hindering industry's ability to begin the implementation of this process.

In the event that a general exemption is not granted for all medical devices except reprocessed devices, B. Braun Medical Inc. proposes that general waivers be granted for small medical devices, as the size does not permit for a legible name, abbreviation or symbol. Additionally, B. Braun Medical Inc. believes that in many cases an attachment to the medical device would interfere with the use of the medical device. There is also a concern that the safety and effectiveness of many other medical devices could be compromised by these requirements. For instance, printing on IV tubing raises concerns of biocompatibility. Also, molding or stamping the name of the manufacturer onto a medical device may compromise the integrity or functionality of the medical device. Based on these concerns, B. Braun Medical Inc. believes that the Agency should work with industry to draft guidance with specific criteria for the types of products that require compliance with Section 301. This guidance should include lists of example product types that would meet the criteria. Below is a list of several product types that B. Braun Medical Inc. believes should be exempted from the requirements of Section 301 based on the rationales described above. This list is not exhaustive, and considerable work between industry and the Agency needs to be completed to fully address the implementation of any exemptions to Section 301.

- Anesthesia needles
- Anesthesia catheters
- IV catheters
- Guidewires
- Vena Cava Filters
- Catheter Introducers
- Stopcocks
- Hypodermic Needles
- Vial Adapters
- Intravascular Administration Sets (tubing and components)
- Convenience Kits

Additionally, B. Braun Medical Inc. believes that the waiver process should embrace the Least Burdensome Practices set forth in FDAMA. In support of this, B. Braun Medical Inc. believes that the Agency should grant exemptions by product type and not by individual product. The waiver process should also be transparent and consistent. Additionally, the waiver process should be monitored to ensure timely response to industry.

Based on the many necessary considerations for the implementation of Section 301 of the Act, B. Braun Medical Inc. requests that the Agency delay the implementation of this section until the Agency and industry can develop guidance on this issue. Until this guidance is created, it will be difficult if not impossible for industry to begin implementing all of the changes that the legislation currently implies. The implementation date should then be set based on interactions between the Agency and industry to identify a reasonable and effective time line. As noted previously, it is not feasible or practical for many medical device companies to complete these changes by the current effective date defined in the legislation.

B. Braun Medical Inc. appreciates the opportunity to comment on the implementation of Section 301 of the Act, and looks forward to continuing open communication with the Agency to develop guidance and practices that will best address the implementation of the Act.

Sincerely,

Rebecca A. Stolarick
Associate Director, Regulatory Affairs
B. Braun Medical Inc.