PHILIPS

Philips Medical Systems

1624 '03 AUG 19 A9:01

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

Re: Docket 03D-0226: Draft Guidance for Industry and FDA Staff—Compliance With Section 301 of the Medical Device User Fee and Modernization Act of 2002—Identification of Manufacturer of Medical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

18 August, 2003

To Whom It May Concern:

Philips Medical Systems, Cardiac and Monitoring Systems is submitting comments to the proposed FDA Docket 03D-0226 (Draft Guidance regarding the Identification of Manufacturer of Medical Devices).

We believe that this guidance adversely impacts patients and medical device users in addition to medical device suppliers, distributors and manufacturers. The following table describes our issues, impact assessments, and recommendations:

#	Issue	Impact	Recommendations
1	The new requirement states that the device will be deemed misbranded "unless it or an attachment thereto prominently and conspicuously bears the name of the manufacturer of the device..." The intended value of labeling each device is not mentioned and it is not clear if each component or accessory is included in this	Manufacturers, contract manufacturers and suppliers will have production process changes, tooling changes, and packaging changes that will: 1)increase overall manufacturing costs, 2) jeopardize supplier contracts, and 3)cause production delays that will result in compromised inventories, marketing delays, and additional costs to products.	The Guidance should indicate why this Regulation is required (i.e., what is it intended to accomplish). We agree with comments submitted to Docket 02N-0534 that the intention of this regulation was for reprocessed devices. We recommend that the scope of this guidance document be for reprocessed devices only.

2003D-0226

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#	Issue	Impact	Recommendations
	regulation.	These impacts could result in discontinued products and/or short-supplies to end users and patients, and will ultimately increase healthcare costs. This new Regulation imposes different labeling requirements from the EU (CE marking allows only the labeling of one responsible manufacturer on the device). This FDA requirement will now force manufacturers to have 2 different inventories (one for US and one for rest-of-world) based on labeling requirements, further increasing costs of the products.	We recommend harmonizing more with the EU Directive system in which devices whose "responsible" person/manufacturer (vs. actual manufacturer) is the listed party on the immediate packaging and accompanying labeling. The immediate packaging and accompanying labeling information is sufficient for product traceability.
2	It is not clear how to handle the labeling requirement in the case of "manufactured for" or "distributed by" or re-labeled/OEM product. In these instances, whose name should be on the device? How are dual-branded products to be identified (e.g. the listing of 2 manufacturers' names for co-developed or co-marketed products)?	End users could become confused if the labeling on the device itself is different than the labeling on the immediate packaging or accompanying instructions. This can potentially create a safety concern if the user contacts the wrong company for vigilance reporting, customer assistance, troubleshooting, and ordering emergency supplies. In many cases OEM suppliers are competing with other companies in the very same markets with the very same products (e.g., company A, company B and OEM all sell the same initial product but companies A&B have their own label on the product). In such an instance, it is financially and competitively disadvantageous for a company to reveal the actual manufacturer on the product as this could undermine marketing efforts by revealing to customers the alternative sources of these products. This empowers customers to go shopping elsewhere and potentially purchase a different product than originally intended for the device (customer confusion). Devices could have limited spacing	We agree with comments to Docket 02N-0534 in that FDA needs to clearly define what is meant by "manufacturer" (21 CFR Parts 801, 807, and 820 have different meanings). If what is actually considered in this regulation is the "responsible" person/party, then this should be made clear in the requirements. Information must be provided in the guidance to handle situations such as "manufactured for", "distributed by", re-labeled/OEM products. Additional information on dual-branded product should also be included.

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		to allow dual-branding; selecting one company over the other can result in contract and legal issues that could impact availability of the product and increase healthcare costs.	
3	Prescription Use devices vs. non-prescription use (e.g., OTC, non Rx home-use devices) need different levels of control.	End users could become confused if the labeling on the device itself is different than on the immediate packaging or accompanying instructions. This can potentially create a safety concern if the end user contacts the wrong company for vigilance reporting, customer assistance, troubleshooting, and ordering emergency supplies. Unnecessary costs will be added to both OTC, IVD and Rx devices since current regulations allow for adequate control and traceability.	It is unclear if the Guidance refers to Prescription Use Only, OTC/Home Use devices and if these devices can be handled differently. Prescription Use devices are handled by prescription or formal Purchase Orders, which are controlled per current Regulations. Additionally, IVDs and Home Use devices also have other labeling requirements that render them equally controlled and traceable. We feel that current regulations for medical devices are sufficient and that this Guidance should be aligned more for the re-use of Single Use Devices and not all medical devices.
4	There was no definition or guidance as to what would qualify for a waiver or the information required for submitting a waiver.	Applications for waivers compound the time delays for releasing product to market, in addition to the current delays imposed by PMA/510(k) applications. This could add unnecessary costs and delays to manufacturing processes, thereby adding costs to the product and negatively impacting delivery to customers.	A clear definition of the waiver process is required. Likewise, a complete list of products already considered "waived" should be contained in the Guidance document. Waivers should be assessed by the FDA Secretary within 10 calendar days so that manufacturers can assess the impact to their programs.
5	The current business climate of mergers, acquisitions and partnerships has created multiple situations where products are getting re-named and old manufacturer names are obsoleted. The Guidance does not address re-branding.	Companies can be merged, acquired or split multiple times over a 5-year period. Forcing manufacturers to label each product will add to end user confusion as the business changes, and adds costs by mandating tooling, dye, and packaging changes.	Guidance on how company name changes can be handled in regard to individual product labeling must be presented in the document.
6	It was not clear in the Guidance if older accessories or components when introduced with new products are still considered exempt from the Regulation or if these older accessories and components now become "newly introduced" as a result of their use	If accessory products or components that are currently exempt now become "new" with a new device, end users would need to buy new accessories even though older labeled product is just as safe and effective. This will result in labeling confusion by the end user and increase	This Guidance should clearly state that old components or accessories are exempt from this Regulation when they are introduced with new devices. If older components or accessories are not exempt, there needs to be information in the Guidance document

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	with a new device.	healthcare costs. Manufacturers would need to deplete old labeled product, compromising inventories and adding to overall product costs. Some product might have to be discarded so that old vs. new labeling inventory does not get mixed, adding additional and unnecessary costs.	on how the transition will be handled (e.g., how will true misbranding be detectable when there is a mix of old and new labeling in the marketplace).

We respectfully ask that the FDA seriously consider the impacts that the Section 301 Identification of Manufacturer requirement will have on end users and patients as well as the medical device industry. We hope that the FDA will create a final Guidance that will serve the best interests of both the medical device user and industry so as to maintain healthcare costs while at the same time assuring product safety and overall compliance to the Regulation.

Thank you for allowing us the opportunity to comment.

Sincerely,

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