



GE Medical Systems

J. Keith Morgan
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02 JUL 16 12:00

July 12, 2002

Mary C. Gross
Office of Drug Safety
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane, Room 15B-32
Rockville, Maryland 20857

Re: Bar Code Labeling Requirements for Human Drugs and Medical Devices:
Comments of GE Medical Systems (GEMS)
Docket No. 02N-0204

Dear Ms. Gross:

GE Medical Systems ("GEMS") is pleased to provide the following comments for the consideration of the Food and Drug Administration ("FDA") in its development of regulations on bar code labeling for drugs, and possibly also for medical devices, for human use. These comments respond to the agency's notices in the Federal Register of June 18 and June 26, 2002, announcing a July 26, 2002, public meeting on these matters (67 Fed. Reg. 41360, 43068 (2002)).

GEMS, a provider of healthcare technologies worldwide for over 100 years, manufactures and distributes a variety of medical devices, including clinical information systems, patient monitoring systems, and a wide array of complex medical equipment such as conventional and digital X-ray, computed tomography (CT), magnetic resonance (MR), ultrasound and bone mineral densitometry, and positron emission tomography (PET) equipment.

G.E. Medical Systems fully supports the concept of bar coding as a potentially useful mechanism to aid in the reduction of preventable medical errors. GEMS recognizes that the principal target of the rulemaking is bar coding of human drugs to reduce preventable medication errors. However, GEMS believes that, for many if not all medical devices as well, the adoption of bar coding also could offer important public health benefits. Accordingly, GEMS is supportive of the FDA's interest in developing a medical device bar coding system.

Just as development of bar coding for drugs is being undertaken with substantial participation by the pharmaceutical industry, we believe the development of an effective bar coding system for medical devices would benefit from the involvement of the various stakeholders, including device manufacturers, healthcare providers, and patient/consumer groups. Medical devices are offered in many diverse configurations at point-of-care use, ranging from single units to multi-unit systems, from devices that make direct contact with patients to those that do not, and from devices intended for repeated use with multiple patients (such as medical imaging equipment) to devices for use by a single patient. The significant product diversity which exists within the medical device industry presents distinct bar code labeling challenges, which need to be specifically addressed.

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FDA's June 18 notice calls attention to some of the special issues presented by medical devices, including what information should be included in codes, whether all devices or only some should carry bar codes, who bears responsibility for generating bar codes, and what public health or patient safety benefits would derive from bar coding medical devices. These are appropriate issues for consideration, and many more will undoubtedly emerge as the agency evaluates whether to extend bar coding to the diverse array of products falling under the definition of medical device. GEMS believes these issues deserve significant study and thought to ensure that the conclusions reached make sense in a real world context.

Concerning medical devices, GEMS recommends that FDA, at this early stage, focus on three principal questions: whether to develop a proposed bar coding requirement for medical devices, whether to separate the rulemaking on medical devices from the rulemaking on drugs, and how to develop a meaningful process for industry participation. On these questions, GEMS in principle strongly supports the development of a bar coding system for medical devices, and believes a separate medical device rulemaking, facilitated by a collaborative process, would be the appropriate vehicle to accomplish this.

A separate rulemaking on medical devices would help to ensure that FDA obtains sufficient information concerning the issues raised by medical device bar coding. We believe this would be best accomplished by the creation of a collaborative mechanism through which industry representatives, together with healthcare providers, patient/consumer groups, and other interested parties, could share perspectives and data with the FDA. Medical device trade associations, such as the National Electrical Manufacturers Association (NEMA) and the Advanced Medical Technology Association (AvaMed) also could make a valuable contribution to this effort, which should include as a goal the standardization of product nomenclature and identification systems within the U.S., as well as harmonization internationally. Accordingly, GEMS recommends that FDA establish a process for broad and ongoing participation by the medical device industry (and its diverse parts), as well as the other stakeholders, in the development of a proposed rule for bar coding for all or certain medical device products.

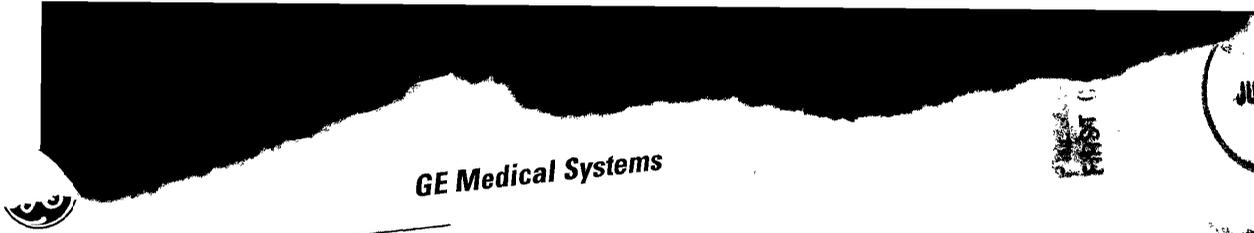
GEMS appreciates the opportunity to provide comments to FDA on the development of bar coding regulations for medical devices and would be pleased to address any questions that the agency may have on these comments. GEMS believes the FDA's medical device bar coding initiative is laudable, and that industry participation is the key to development of a workable and effective bar coding system. GEMS would support and be pleased to participate in, as well as commit resources to, a collaborative process established by the FDA to accomplish this objective. Please feel free to contact me at the address and phone number shown on the letterhead above.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Keith Morgan", with a long horizontal flourish extending to the right.

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cc
Dockets Management Branch (HFA-305)
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