AdvaMed
Advanced Medical Technology Association

June 12, 2003

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

Re: Docket No. 02N-0204: Bar Code Label Requirement for Human Drug Products and Blood

Dear Sir or Madam:

AdvaMed is pleased to provide comments on the Food and Drug Administration's (FDA's) publication of the Proposed Rule on Bar Code Label Requirements for Human Drug Products and Blood. AdvaMed, the Advanced Medical Technology Association, represents more than 1,100 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the $71 billion health care technology products consumed annually in the United States, and nearly 50 percent of $169 billion purchased around the world annually.

AdvaMed has a number of general comments.

AdvaMed applauds FDA's decision to defer action on medical device bar coding for the reasons identified in the preamble to the proposed rule. A regulation tailored to drugs and biologics would not recognize the unique issues posed by medical device technologies, such as the diversity of products, the evolution of coding technology, and the unique product identification needs often negotiated between customers and device manufacturers.

Most medical device manufacturers who are voluntarily labeling their products today use the Universal Product Number (UPN) system. The Uniform Code Council (UCC)/European Article Number (EAN) Standard and the Health Industry Bar Code (HIBCC) Standard do not conflict and together they comprise the UPN system. Additionally, the National Drug Code (NDC) data structure is a subset of the UCC/EAN Standard, and therefore, included in the UPN System. Should FDA begin to consider any application of bar coding for medical devices, AdvaMed urges FDA to endorse the UPN system.

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Scanners that are commercially available today are able to read a variety of symbologies. AdvaMed urges FDA to refrain from setting specifications on technology, as this would lead to the adoption of older and more limited ways of identifying products, thus "freezing" the evolution of automatic identification technologies.

AdvaMed further recommends that FDA adopt the use of the term "automatic identification" in lieu of bar coding because the term bar coding refers to the linear bar coding system. While traditional linear "bar code symbologies" on retail packages are easily recognizable, there are other configurations of automatic identifiers, such as matrix symbologies and radio frequency identification technology (RFID). AdvaMed believes that the use of the term bar coding could inappropriately lock industry into one standard, one symbology, one data structure, or one technology while other alternatives continue to evolve rapidly. The phrase "mandatory bar coding" fails to account for existing automatic identifiers and existing hospital systems that currently rely upon their preferred code standards, symbology, data structure, languages, or technologies to meet their particular needs.

In addition AdvaMed offers more specific comments on the following topics:

1. Automatic Identification Technology is Evolving
2. Automatic Identifiers Should Be Voluntary
3. Automatic Identification Coding Systems Should be Voluntary
4. Applying an Identification System to Blood & Blood Components

1. Automatic Identification Technology is Evolving

AdvaMed recommends that FDA allow the use of nonlinear bar codes to facilitate voluntary and/or market driven product automatic identification. While traditional bar codes on retail packages are easily recognizable, there are other configurations of auto-identifiers, including matrix symbology and RFID, which uses an imbedded chip. All of these technologies can use various data structures under the UPN system, and most modern scanning technology can read them all. Because these technologies will continue to evolve, AdvaMed refers to automatic identification rather than bar coding, which could inappropriately lock industry into one standard, one symbology, one data structure, or one technology. The phrase "mandatory bar coding" may fail to account for existing auto-identifiers and existing hospital systems that currently rely upon their preferred code standards, symbology, data structure, languages, or technologies to meet their particular needs. Moreover, due to inevitable technology evolution, many of the bar code symbologies may not be best suited for a long-term intended use model.

AdvaMed members are currently integrating automatic identification into medical devices. Our members are using the best technology for the required results, which may include 2D or Matrix symbologies and RFID, in addition to bar codes. Therefore, our members recommend

that the technology choice be left up to the industry and their partners and customers. Also, given the small number of hospitals that have actually implemented data capture solutions, the risk of misspent funds is minimal. AdvaMed members would like the opportunity to advise their customers about technology solutions to ensure that the best solutions are implemented.

2. Automatic Identifiers Should Be Voluntary

AdvaMed recommends that FDA allow the voluntary use of UPNs on medical products, which allows for the use of industry-approved UCC/ EAN or HIBC standards – a decision that reflects the clinical use of devices, the interests of healthcare professionals, and the challenges faced by manufacturers in auto-identifying medical technology. The UPN system provides greater consistency with global identification trends. The proposed rule requires the use of the NDC system on drug products, which is part of the UPN system but would not be appropriate for medical devices. The NDC is a pharmaceutical-based numbering system exclusive to FDA and, if applied broadly to other medical products, could force an overhaul of current identification practices for the medical device industry or, at a minimum, result in confusion over the use of multiple product identifiers on products sold both domestically and internationally.

Audits of products in labelers' warehouses, carried out by the Health Industry Distributors Association (HIDA), indicate that over the period from 1995 to 1997 there was an increase of approximately 30% in the use of UPNs on devices at the "unit of use" level, and an increase of approximately 17% at the shelf-pack level. Unfortunately these data are old, and there is a need for updated, unbiased surveys that look at not only the number of UPNs on devices, but also the extent to which healthcare professionals utilize the products that are coded and why they do so. Even so, available data confirm that manufacturers – even without regulation – increasingly are auto-identifying medical products.

Decisions are best made when manufacturers work with healthcare professionals to clearly identify the goals and practical limitations of auto-identification. They may ask how a device is used, how often it is used, and how it is packaged. The manufacturer will consider lot size, device and packaging size, and surface material. They will consider how hospital protocols might be changed by the use of UPNs, which data structure might be appropriate, and at what level of packaging UPNs should be used. All this is a process to determine whether the expected benefits warrant the additional burden to the health care system. Firms use UPNs on devices for various reasons. Most temporary and permanent orthopedic implants, for example, are auto-identified to provide traceability. Other products are auto-identified to assist in inventory control.

3. Automatic Identification Coding Systems Should be Voluntary

AdvaMed believes that automatic identification coding systems should be voluntary for medical devices. Under the current voluntary system, device manufacturers and customers agree on appropriate automatic identification standards, packaging levels and devices to meet customers' needs. Firms already have auto-identified thousands of devices, and they will continue to work with customers to decide which other products should be auto-identified. It is a dynamic process that moves forward – albeit deliberately – in a way that is responsive to customer needs and is cost effective, employing UPNs selectively where benefits can be realized.

It is important to note that automatic identification of medical products is not a panacea to resolve many of the medical errors or inventory management challenges. All stakeholders – FDA, hospitals, providers, risk managers, and manufacturers – must recognize that encoding is but one piece of an overall system that requires a commitment to scan products, update encoded information, and analyze data if benefits are to be realized. Providers, therefore, must commit to processes that use these auto-identifiers, and there must be a system to maintain and analyze the data collected. Merely putting machine readable information on a device does not reduce medical errors, nor does it improve inventory control.

Furthermore, a UPN is one piece of a system that requires a commitment to scan products, identify patients, update encoded information, and analyze data if benefits are to be realized. Increased patient safety may be attainable for only a subset of medical products, depending on the nature of the device and its use in a clinical setting.

Voluntary automatic identification of a product's "unit of use" should be determined by the customer and the manufacturer. There are differing opinions on whether it is practical or necessary to apply automatic identification encodation on every "unit" of medical products. Encoding at the unit of use is dependent on the situation between a customer and the manufacturer, the volume of product produced, and the size and cost of the product. For example, the design or the cost of the product might either prohibit or negate unit of use encoding. Additionally, encoding each unit may be impractical and would not be beneficial in controlling inventory costs or tracking clinical outcomes.

AdvaMed also recognizes that the voluntary inclusion of the expiration date or lot, batch or serial number may be appropriate for certain medical devices products. AdvaMed believes that for some medical devices the voluntary inclusion of this secondary information will benefit the automatic identification system. In certain situations the availability of this secondary information will provide healthcare professionals with access to accurate patient information. While it is possible to include this information on bar codes on some medical products, this information can easily be included and read using RFID technology.

AdvaMed recommends that FDA support a voluntary automated identification system that allows manufacturers the flexibility to meet customers' needs while harmonizing to existing national and international coding automatic identification initiatives and thus avoid hospital-established systems that could be problematic. There is no standard that satisfies the requirements of all hospitals and customers. Although most modern scanning equipment can translate industry-approved HIBC and UCC/EAN data structures, and some can read both bar codes and RFID, hospitals and customers often have their own encoding systems and print their own unique encoded labels. These labels may not conform to any industry standard. Therefore, AdvaMed recommends that individualized, hospital-generated systems not drive any industry automatic identification initiatives.

4. Applying an Identification System to Blood & Blood Components

AdvaMed recommends that FDA continue to allow manufacturers of blood and blood components to use the uniform labeling standard (United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using International Society for Blood Transfusion (ISBT) 128) to assist them in complying with labeling requirements under 21 CFR 606.121(c)(13). The blood industry has worked over the past decade through the International Council for Commonality in Blood Bank Automation to standardize critical elements needed to improve the safety of the blood supply. These standards have been recognized by FDA in its June 2000 Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components June 2000. In the guidance, FDA noted that conformance to ISBT 128 would "facilitate uniform labeling of blood and blood components in the United States and internationally." In addition, the American Association for Blood Banks recognized the ISBT 128 format within their Standards for accredited blood banks (Standard 5.1.6.3). The data structures and label standardization are used for consistency in electronic transfer of data to information systems and consistent placement of critical information on blood products. Not only has the ISBT 128 data structure and coding system been the migration system accepted by the United States Blood Banks, but it has also been accepted by the Canadian and European Communities.

If another data format were mandated, blood bag manufacturers would need to provide multiple product codes for the same product based on the bar code system, and bag label layout, used by the individual customer. This would increase the cost of labeling, manufacturing and inventory controls. Additionally, the UCC/EAN format is not associated with any particular layout, which is essential for error reduction in blood banking and addressed by ISBT 128.

Due to the potential impact on labeling, manufacturing, and inventory controls it would not be feasible for blood banks to maintain multiple standards. If an improved standard is chosen, an extended transition period would be required to allow for use of both the existing

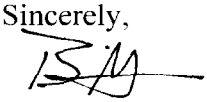
and the new system being implemented. Intensive training of both Blood Center and Hospital staff would also need to be provided.

Summary

AdvaMed strongly supports FDA's decision to exclude medical devices from the proposed rulemaking. AdvaMed requests that FDA consider several important recommendations while finalizing the rule. AdvaMed urges FDA to adopt the use of the term automatic identification instead of bar coding to encompass the wide range of technologies currently available to the healthcare industry and the emerging technologies in this area. Additionally, AdvaMed recommends that FDA allow the industry and the marketplace to determine which technologies are used.

Finally, AdvaMed recommends that FDA continue to involve stakeholders as it proceeds to develop the final rule to require bar codes on human drugs and blood and as it considers any application to medical devices. This issue raises many important issues and concerns that warrant stakeholder involvement. AdvaMed appreciates the opportunity to provide these comments and would like to work with the agency to ensure the appropriate implementation of this key Secretarial initiative.

Sincerely,



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