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Food and Drug Administration
5630 Fishers Lane, Room 1061
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To Whom It May Concern:

Attached is AIM Global's response to the FDA proposed ruling on bar coding human drug products and biological product labels.

An electronic copy of this response was submitted on Thursday, June 12, 2003.

Sincerely

Daniel P. Mullen
Interim CEO

Docket Number 02N-0204

Proposed Rule: ***BAR CODE LABEL REQUIREMENT FOR HUMAN DRUG PRODUCTS AND BLOOD***

Response from:
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AIM Global founded in 1974 is committed to standards development, education and market promotion. With a global membership of over 900 companies that provide Automatic Identification and Data Capture (AIDC) hardware and software. AIM represents a constituency with expertise in bar code (linear and two-dimensional) and many other automated data collection technologies. With offices in the United States, Belgium, and Hong Kong, AIM Global has a keen appreciation for the global impact of the regulations now being developed by the FDA. We stand ready to leverage this vast network of organizations to ensure understanding and smooth implementation of the new regulations.

AIM Global members participating in the development of this response include:

Brady Corporation
DATA2, Inc.
Datalogic S.p.A.
Datamax Corporation
Dynic USA Corporation
EMS Wireless
HHP Inc.
Intelligent Instrumentation, Inc.
International Bar Code Systems,
Intermec Technologies Corporation
Lowry Computer Products
Printronix, Inc.
Product Identification and Processing Systems, Inc.
Zebra Technologies Corporation

Disclaimer: This AIM document stands as the consensus work of an industry group that represents multiple automatic identification products and technologies. The appearance of a member company as a supporter of AIM's response does not and should not imply that our member companies do not have divergent views and/or further statements and recommendations that they would like to make to the FDA on behalf of their individual organization. For the specific recommendations and comments attributable to any individual organization represented herein, please reference the submission of that particular organization.

Since the earliest days of AIM Global, the association has led the development of open bar code symbology technical specifications that are now referenced by a multitude of application standards. Symbology specifications have been developed by a team of the leading scientists in the industry and rigorously reviewed by all interested parties. The specifications provide sound technical, non-proprietary information that is the basis for the development of dependable, open bar code systems. Bar code equipment, software,

and systems developers continue to depend on these specifications. In addition to the healthcare industry, the electronics, retail, telecommunications, and automotive industries as well as the Department of Defense rely on AIM for technical specifications and technical standards. AIM has also been a major contributor to the development of global bar code standards. As a leading advocate of open standards, AIM was instrumental in the creation of ISO/IEC JTC1 SC31, the committee responsible for the development of international standards for *Automatic Identification and Data Capture Techniques.* At this time AIM is a key liaison to this committee and to the Secretary for Working Group 1, the work group responsible for the development of data carrier (i.e. bar code) standards internationally.

AIM Global believes that many of the important issues in the proposed regulation are best influenced by members of the pharmaceutical supply chain. AIM Global's input, therefore, will focus on the technical aspects of the proposed regulations especially as they relate to the use of bar codes.

We wish to first and foremost recognize the tremendous amount of work required of the FDA in order to develop a proposed rule that has been generally accepted by the industry. In our review of the proposed rule and participation by some members in the Industry Coalition on Patient Safety (ICPS), we recognize that the industry is still developing an understanding of bar coding, automatic identification and data capture. AIM Global, working with a cross section of our members, would be pleased to serve as an unbiased technical resource to the FDA as the regulations are finalized. This would help assure that the final regulations are technically feasible today and structured to accommodate changing needs within the pharmaceutical industry changes in the EAN.UCC system and emerging technologies.

Because of AIM Global's expertise we have chosen to comment on selected technical questions in Section VIII, Request for Comments.

> *Q1. Whether we should require bar codes on prescription drug samples, and the costs and benefits associated with such bar codes.*
>
> While we believe the question of requiring bar codes on samples is a decision best left to the FDA and the pharmaceutical supply chain, we believe there are few technical reasons to exclude physician samples from the bar code regulations. For example, in many cases sample packaging is larger than that used for unit dose making it less of a printing challenge to incorporate a bar code.
>
> Developing plans for an efficient bar code labeling system requires a manufacturer to look at all packaging levels for a product even if they are not planning to apply bar codes to all levels. Rather than considering regulations related to the bar coding of samples at a later date, it may actually be more helpful for the industry and especially the pharmaceutical manufacturer if bar coding of samples is included in the regulations even if the date for compliance is later than the proposed three years for unit-of-use and unit dose.

Q4. *Information on the costs and benefits associated with putting lot number and expiration date information in the bar code.*

It is technically feasible to print lot and expiration date bar codes on many unit dose products today. In fact, very small bar codes have been used for product identification in the electronics and automotive industries for several years. Although the secondary data of lot and expiration dates will add benefits to the supply chain, costs will vary greatly and the pharmaceutical industry would have to determine if this additional data would reduce medication administration errors

On some products, in some line configurations, the cost to print lot and expiration information will be minimal. In some cases, it will be an expensive addition. AIM Global would suggest that manufacturers review the following issues when considering whether to bar code lot and expiration date.

Market Needs

Are my customers asking for it? Is it beneficial to their internal processes?

Product

- How big is the product/package?
- What barcode symbology are you trying to print? Will the information to be printed in the bar code be variable?
    - How many images, per minute, per shift, per batch, per month, per year?
    - How big is the image?
- Is the information available in advance to allow for preprinted labels? Or, is on-site printing required?
- Is there a space constraint?
- Can you print directly on the package?
- Can you use a label?
    - Are special inks or labels required?

Facility

- How is your facility equipped? How much room do you have?
- What are your line changeover requirements?
- Are you printing batch or on demand?
    - What are your testing requirements?
    - What are your requirements for verification and validation?
- What will you monitor during the printing process?
- What do you require for reliability of the equipment that you will print from?
    - What are the scheduled maintenance requirements?
    - How/when is service available?
- What ROI considerations do I have?
    - How long will this solution be in place?

- Will the line shrink or grow? How quickly?
- Will the line be replicated? At this location or others?

Q5. *Whether the rule should refer instead to linear bar codes without mentioning any particular standard or refer to UCC/EAN and HIBCC standards.*

From our experience in implementing standards in other industries, AIM Global believes that the regulations should be based on industry approved data structures. This will ease the burden of compliance by offering a flexible structure that would allow a pharmaceutical company to choose the symbology right for their company, their products and their customers. Further, use of an industry approved data structure will facilitate implementation by hospitals. In the case of bar coding pharmaceutical products, AIM Global supports the selection of the EAN.UCC system. However, to assure that those responsible for developing labeling systems and those developing scanning systems apply the standard correctly, we encourage the FDA to include a statement referring users to the EAN.UCC guidelines for clarity and assistance. The guidelines can be accessed through www.uc-council.org.

We fully support the recommendation of the use of the EAN.UCC system for the bar coding of pharmaceutical products. However, if the FDA begins considerations for the bar coding of medical devices it will be important that the application needs of that segment of the industry be taken into account before decisions regarding specific bar code standards are made. AIM Global would welcome the opportunity to assist the FDA in that endeavor.

Q6. Additional information regarding bar code scanning technology and the ability of bar code scanners to read different symbologies.

The FDA has put a lot of emphasis on bar code scanners, citing costs and technology trends. It appears that the FDA has used scanning technology as a basis for symbology standards. AIM Global would like to point out that although scanning is an important part of a patient safety system, hardware as a category is just a fraction of an enterprise wide system, and a patient safety system is expected to be similar. Hospitals will need to install enterprise system infrastructure, software and databases that will be the majority of the system costs.

Users of bar code technology are <u>not</u> limited to a specific scanner or a single symbology. For many years bar code readers have been able to read multiple symbologies. This capability, called auto-discrimination, is commonplace in today's scanner market. AIM Global members that deliver hand held scanners to the market confirm auto-discrimination is a standard characteristic of hand held bar code scanners currently sold. The range of bar codes read by an auto-discriminating reader may vary from several to dozens depending on the reading technology. It is possible to configure a reader to intentionally read a limited number of bar code types in an application.

The FDA has expressed concerns about the impact of the proposed regulations on hospitals if image scanners are needed. It is likely that a variety of scanners will be used by hospitals to support a variety of applications. However, a trend of performance improvement and cost basis reduction has moved two-dimensional bar code reading technology from a specialty solution to a technology that is currently deployed in mainstream applications.
To ensure the best performance of a bar code system we point out that the quality of a bar code symbol image is just as important as the scanning technology. Extensive print quality standards for bar codes already exist nationally, internationally and within the EAN.UCC system. These documents set forth metrics for determining bar code quality and, ultimately, assuring the ability to scan bar codes at the point of use. Those who are responsible for creating bar code images should be encouraged to have processes in place to veify bar code image quality.

Q7. Whether the rule should adopt a different format (whether that format is a symbology, standard, or other technology), considering the following issues:

- *What other symbol, standard, or technology should we consider, either in place of a linear bar code or in addition to it?*

  AIM Global fully supports the adoption of the EAN.UCC system. As explained above in Q5, as long as the data encoded in the data carriers follows the guidelines established by EAN.UCC, hospitals will be able to read them. User standards should be technology independent. In order to assure that the regulations will allow for technology to evolve, we would urge the FDA to remove the specific reference to "linear" since it is currently specified within the EAN.UCC system.

  Working within the EAN.UCC system technology innovation, market forces and the standards development process will all continue to provide the guidance necessary to have machine readable symbols that can be used throughout the pharmaceutical industry and in particularly at patient bed side.

- *How accepted is that symbol, standard, or technology among firms that would have to affix or use that symbol, standard, or technology?*

  In Q6, the capability of laser and image scanners to auto-discriminate was explained. That capability exists because there are international technical standards for these bar code symbologies. It is important to distinguish between ISO technology standards and application standards such as the EAN.UCC system, which specify how particular symbologies will actually be used.

  Before becoming a part of an application standard such as the EAN.UCC system, a symbology goes through an open and rigorous development and review process. The development process for international standards for both bar code symbologies and for the measurement of bar code print

quality is actively supported by AIM Global and representatives from many countries.

The EAN.UCC system is the most widely accepted system around the world for manufacturers of consumer products. It is already used by many pharmaceutical manufacturers on many packaging levels including unit dose. This open system approach helps assure that the hardware and software (bar code printers, scanners, verifiers and bar code label software) is widely available at a reasonable cost.

- *Will hospitals be able to read or use the symbol, standard, or technology, either with existing equipment or equipment under development?*
  For the reasons identified above, as long as pharmaceutical manufacturers follow the EAN.UCC guidelines correctly when applying bar coded product identification and hospitals establish data bases that follow the established criteria, they will be able to read and store the bar coded data using bar code equipment on the market today. To further ensure that hospitals will be able to read the bar codes, manufacturers (and all entities responsible for generating bar codes) should be encouraged to have procedures in place that include measuring bar code image quality.

Q10. *Whether we should require the use of ISBT 128 for blood products, a specific symbology that is consistent with that required for drugs in §201.25, or "machine readable symbols" as approved by the Director of CBER.*

Current FDA regulation 29 CFR 606.121(c)(13) states that the container label for blood and blood components "*may bear encoded information in the form of machine readable symbols approved for use by the Director, Center for Biologics Evaluation and Research.*" In 2000, the *ISBT 128* bar code system, version 1.2.0, was approved for use by the FDA under 29 CFR 606.121(c)(13).

Experts on Bar Code technology from the AIM Global membership were involved in the development of *ISBT 128.* In addition, Dr. Clive Hohberger, an AIM Global member, was Editor of the *ISBT 128* Standard for more than 6 years and managed its acceptance by the AIM Technical Symbology Committee, ANSI/FACT standards, and as part of the ISO 15417 Code 128 symbology standard.

AIM Global believes that FDA regulation 29 CFR 606.121(c)(13) was visionary, in that it was intended to be flexible in terms and to accommodate the development of future machine-readable technologies, although the term "symbol" then implied bar codes. AIM Global also believes that the regulation should be looked upon as including by extension other emerging machine-readable data carriers such as wireless radio frequency identification transponders (RFID tags) for use as a supplement to bar codes.

As was pointed out in the response by ICCBBA, the essential feature of *ISBT 128* is that the data structures of *ISBT 128* are technology independent, and thus provide the FDA with a framework in which future machine-readable technologies such as RFID transponders can be accommodated without the need for major redesign of either data structures or information processing systems. Adoption of *ISBT 128* thus leverages the introduction of future advanced machine-readable data carrier technologies, which, in parallel with *ISBT 128* bar codes, could provide additional medical and safety benefits in blood transfusion.

ISBT 128 utilizes the same underlying bar code technology used within the UCC system in UCC/EAN-128 bar codes, namely the ISO 15417 Code 128 bar code symbology. Nearly all bar code readers and bar code printers supporting ISO Code 128 also support both *ISBT 128* and UCC/EAN-128. Furthermore, *ISBT 128* bar codes were designed to coexist in the same usage environment as UCC/EAN-128. Bar code symbols and data structures are unique and completely differentiated within the respective standards: All UCC/EAN-128 bar codes start with a FNC1 character; *ISBT 128* bar codes start with a "=" or "&" character. This was done in the design of *ISBT 128* to ensure that drug products labeled using the UCC system bar codes and *ISBT 128*-labeled blood products can be used freely in the same environment without risk of confusion. Therefore, there is inherent compatibility between these two bar code systems.

The difference between *ISBT 128* and UCC/EAN-128 bar codes lies in the system of internal data structures stored within the bar code, each of which are highly optimized for their applications. While the UCC system is focused on object identification and supply chain management, the *ISBT 128* data structures focus on individual unit donation identification and contain extensive information describing the biological properties and prior processing history of that particular unit of blood product, information essential to safe transfusion. These compact, internationally defined *ISBT 128* data structures were developed over a decade by the ISBT Working Party on Automation and Data Processing, and were designed to communicate the maximum amount of medically significant and safety-related information in language-independent bar codes in a minimum of label space. As blood is now used internationally in commerce, in times of war and for disaster relief, transfusion safety is best served when an internationally standardized and accepted system of blood labeling, such as *ISBT 128* is used.

To remain viable bar code standards must be maintained and managed. In the United States the EAN.UCC system is maintained by the Uniform Code Council through fees assessed to product manufacturers. The ISBT 128 system is supported by the International Council for Commonality in Blood Banking Automation, Inc. (ICCBBA), a non-profit organization, through fees assessed to blood collection agencies and organizations that are involved in printing the blood labels. With regard to the efficacy of this approach for financially supporting the organization, AIM Global does not offer an opinion and would defer to the global blood banking community as to its value. However, AIM Global does support the management of standards via professional organizations both to ensure the

integrity of the standards are maintained, and that systems continue to evolve in a controlled manner to accommodate on-going and new, global user needs.

AIM Global member companies therefore support that *ISBT 128* bar codes be mandated for use with blood and blood component labels.