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November 4, 2010

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

Re: Comments of AIM, Inc
Docket No. FDA-2010-D-0426
"Guidance for Industry, Bar Code Label Requirements—Questions and Answers (Question 12 Update)"

Gentlemen:

We are pleased to submit the enclosed comments regarding the above referenced docket which appeared in Federal Register Vol. 75, No. 172 pages 54347-8.

These comments were prepared by members of the AIM Technical Symbology Committee (TSC). The TSC has developed the public domain International Technical Specifications for virtually every linear bar code and 2-dimensional symbology in common use, including those in the GS1 System. AIM TSC Members then led the codification of many of these symbologies into ISO/IEC standards. The TSC is more than a standards writing committee; it is in fact the world's leading research group on symbology design and symbol quality measurement.

We strongly support and commend the FDA for its on-going program to implement automatic identification technologies for the identification and tracking of healthcare products.

As technical experts in the field of both linear bar codes and 2-dimensional symbologies, AIM will be happy to respond to any technical support requests from the FDA about implementation.

Sincerely yours,

Clive P. Hohberger

Clive P Hohberger, PhD
Chairman of the Board
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FDA-2010-D-0426

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Submission by AIM to the FDA in Response to Request for Comment Concerning FDA's Draft Guidance:

"Guidance for Industry: Bar Code Label Requirements—Questions and Answers (Question 12 Update)"

Docket No. FDA-2010-D-0426

AIM is the international trade association representing automatic identification and mobility technology solution providers. AIM is also the worldwide authority on linear bar code and 2- dimensional symbologies. AIM members are providers and users of technologies, systems, and services that capture, manage, and integrate accurate data into larger information systems that improve processes enterprise-wide. Serving members in 43 countries for 35 years, the Association has developed key technical specifications and guidelines that support the use of auto ID and mobile IT solutions. Industries that participate in our standards development process include aerospace, automotive, consumer goods, healthcare, government, high-tech, and transportation and logistics.

Support for the Use of Two-Dimensional Symbologies on Vaccines

Consistent with our submission of 12 June 2003 in response to FDA's request for comment on the original proposed rule for "Bar Code Label Requirements for Human Drug Products and Biological Products" (Docket Number 02N-0204), AIM supports the move by FDA to broaden the application of the GS1 System (formerly EAN/UCC) General Specifications and relevant GS1 System application guidelines to permit the use by prescription drug (and certain OTC drug) labelers of two-dimensional bar code symbologies specified by the GS1 System as an alternative to the linear symbologies to which they are currently restricted under *"Bar Code Label Requirements for Human Drug Products and Biological Products; Final Rule"* (69 FR 9120).

AIM recognizes the scope of the current draft *"Guidance for Industry: Bar Code Label Requirements—Questions and Answers (Question 12 Update)"* is intended to apply to vaccine manufacturers only and we applaud FDA's willingness to consider requests from vaccine manufacturers who request to use alternate coding technologies, such as two dimensional symbologies, that encode basic item identification (e.g., a GS1 System Global Trade item Number with embedded NDC), plus, for example, lot number and expiration date information, for an exemption pursuant to 21 CFR 20 I.25(d)(l)(ii) to the linear bar code requirement. ***AIM believes such updated guidance should be issued as promptly as possible in accordance with FDA's due process requirements. However, we also believe that industry guidance on the choice of 2-dimensional symbology is required now to support this and other FDA initiatives.***

The FDA guidance for Industry *"Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages"* dated March 2010 recommended the use of a serialized NDC number (sNDC) for most prescription drugs and another recognized standard such as ISBT128 for certain biological products such as blood, tissue and cellular products. The use of the GS1 serialized GTIN

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[1], with the NDC number embedded within the GTIN, is one recommendation among several accepted and interoperable options recognized within ISO/IEC 15459, *"Information technology—Automatic identification and data capture techniques—Unique identification"*. Other secondary product attributes (beyond serial number) such as expiration date and lot number, for example, can also be optionally encoded. This sNDC data structure is very similar to that desired for vaccine 2-dimensional symbols.

DataMatrix ECC 200, of which one form is GS1 DataMatrix [2], is specified within ISO/IEC 16022:2006 DataMatrix [3], a 2-dimensional error-correcting symbology standard in which AIM took the leading development role. DataMatrix ECC 200 supports the data structures required for vaccine labeling, sNDC, and the FDA's UDI initiative. DataMatrix ECC 200 symbol usage is also explicitly supported by HIBCC and ISBT128 standards. Thus DataMatrix ECC 200 provides an internationally accepted and open standard that can support all active FDA initiatives in drug, biological and device bar coding with higher reliability and greater capacity than any linear bar code symbology.

In addition, mass serialization of labels, packaging or devices is only possible if each symbol can be uniquely produced and directly marked at pharmaceutical production line speeds. The aerospace industry has worked for a decade on the problem of producing directly marked DataMatrix ECC 200 symbols, and the symbol quality issues that result from the required production processes. Technical experts from AIM's Technical Symbology Committee (TSC) took industry leadership in the development of ISO/IEC TR24720:2008 *"Guidelines for Direct Part Marking"* [4] and the *"AIM Direct Part Marking Quality Guideline"* [5], enabling the use of directly marked DataMatrix ECC 200 symbols on both packaging and objects. The Department of Defense and NATO have standardized on DataMatrix ECC 200 for the IUID (Item Unique Identification) programs.

No other 2-dimensional symbol has received as much attention as DataMatrix ECC 200 in direct marking applications. Its proven robustness to printing and direct marking processes, reading under difficult lighting conditions, extreme spatial efficiency and broad range of reader support has made it widely used in item labeling standards. ***AIM recommends that the FDA accept and give industry guidance on the use of ISO/IEC 16022:2006 DataMatrix ECC 200 as the preferred 2-dimensional symbology for vaccine labeling.***

Just as FDA restricted pharmaceutical labelers to a subset (linear bar codes) of the available data carriers supported by the GS1 System and HIBCC in the 2004 bar code rule, AIM believes it appropriate for FDA to emphasize the use of Data Matrix ECC 200 as the preferred 2-dimensional symbology for vaccine labeling. Although 2-dimensional bar code scanners and imaging systems that decode Data Matrix ECC 200 can (and many do) also read the other 2D symbologies, Data Matrix ECC 200 is the broad common denominator supported by GS1, HIBCC, ISBT-128, DoD and other possibly relevant standards. There is a clear benefit in giving industry guidance to make ISO/IEC 16022:2006 Data Matrix ECC 200 the preferred 2-dimensional symbology.

Concerning implementation, when a two-dimensional symbology such as GS1 DataMatrix ECC 200 is utilized on vaccines (or beyond, whether on other pharmaceutical products or on medical devices), the FDA must make certain that manufacturers understand that they need to comply fully with GS1 System symbology and data structure standards [6]. Within the GS1 System as it pertains to the U.S.

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pharmaceutical supply chain, the National Drug Code is explicitly embedded within the 12- or 14-digit GTIN primary item identifier and can be explicitly recognized no matter what linear or two-dimensional GS1 bar code symbology is used to represent the data.

Secondary product attributes such as expiration date, lot number and serial number, for example, could also be encoded. Whatever the complement of primary item identification and secondary attributes, a single GS1 System 2-dimensional symbol must include the GTIN encapsulating the NDC as the fundamental data element, with the secondary attribute data elements "concatenated" after the GTIN in a clearly prescribed manner as set out in the GS1 General Specifications [6]. In this way materials management, clinical and other software systems can readily differentiate the discrete data elements encoded in any properly formatted GS1 System bar code.

Recommended Future Guidance on the Use of Two-dimensional Symbologies on Drugs

However, AIM would urge FDA to go beyond a narrow exception for vaccines and, after issuing final guidance on this question concerning vaccines, to establish a sunrise date when manufacturers of all drug and biological products covered by the rule (21 CFR Parts 201, 606, et al.) would be permitted to use a 2-dimensional symbol specified under the GS1 System (or, consistent with the rule, the HIBCC and ISBT128 systems) instead of a linear bar code to which they are now limited. Setting an appropriate future date (at least two years after issuance of the revised FDA guidance) for the optional use of 2-dimensional symbols (in lieu of the current linear requirement) will allow hospitals and other enterprises sufficient time to ensure that their scanning equipment is capable of reading the 2-dimensional symbols.

This would also require the FDA removing the restriction on 2-dimensional symbols under the "*Bar Code Label Requirements for Human Drug Products and Biological Products; Final Rule*", whether though a revision to the regulation itself or revised guidance that provides for permissive use. Again, because it supports all the recommended drug serialization systems, ***AIM recommends that the FDA provide industry guidance that ISO/IEC 16022 DataMatrix ECC 200 be the preferred 2-dimensional symbology, particularly on unit-dose and unit-of-use packaging.***

References

[1] http://www.gs1.org/barcodes/technical/idkeys/gtin

[2] www.gs1.org/docs/barcodes/GS1_DataMatrix_Introduction_and_technical_overview.pdf

[3] http://www.iso.org/iso/catalogue_detail.htm?csnumber=44230

[4] https://www.aimglobal.org/estore/ProductDetails.aspx?productID=516

[5] https://www.aimglobal.org/estore/ProductDetails.aspx?productID=599

[6] http://www.gs1.org/barcodes/technical/genspecs

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