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June 12, 2003

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

Re: Comment on Docket No. 02N-0204
Bar Code Label Requirement For Human Drug Products and Blood, Proposed Rule, *Federal Register*, Volume 68, Number 50, pages 12500-12534 (March 14, 2003).

Dear Sir/Madam:

VISI Subcommittee hereby submits comments to Docket No. 02N-0204, pertaining to the proposed rule on Bar **Code Label Requirements For Humane Drug Products and Blood** published in the *Federal Register,* Volume 68, Number 50, pages 12500-12534 (March 14, 2003).

VISI Subcommittee appreciates the agency's interest in a response to the FDA proposal for electronic identification of Unit of Use vaccine labeling.

We respectively submit the following comments on the proposed rule. Please see below VISI Subcommittee response and supporting Business Case.

Sincerely,

VISI Subcommittee

Aventis Pasteur
Chiron Vaccines
Glaxo Smith Kline
Merck
Wyeth

02N-0204

C60

Industry Forum Subcommittee
Vaccine Identification Standards Initiative

June 12, 2003

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5630 Fishers Lane, Room 1061
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Re: Comment on Docket No. 02N-0204
Bar Code Label Requirement For Human Drug Products and Blood, Proposed Rule, *Federal Register*, Volume 68, Number 50, pages 12500-12534 (March 14, 2003).

Dear Sir/Madam:

This letter on the above noted proposed rule is being submitted on behalf of the Industry Forum Subcommittee of VISI. This Subcommittee supports FDA efforts in reducing medication dosing and transcription errors. The aforementioned subcommittee is comprised of representatives from five of the US drug industry's leading vaccine manufacturing companies. For the past eighteen months this group has been meeting to evaluate many issues regarding RSS bar coding, Data Matrix and product labeling. We have fully evaluated current technology for both the end users of vaccines and manufacturers production lines.

At the FDA Public Meeting on 26 July 2002, a representative of this subcommittee presented the groups comments on the proposed rule, aligning its support with the PhRMA statement. We have researched encoding technology capabilities in the market for printing in small areas on vaccine labels.

As a result of our findings, the VISI Industry Forum Subcommittee recommends that, to efficiently accomplish encoding small size vaccine labels at high speeds commonly seen in production, Data Matrix be accepted as the data structure for the vaccine industry. A supporting business case has been developed and issued to the Uniform Code Council highlighting the advantages the Data Matrix code offers to the vaccine industry.

VISI Industry Forum Subcommittee Response to the Specific Questions Posed by the FDA:

FDA is soliciting responses to a series of questions, as seen on page 12529 of the proposed rule. Our responses follow in dark blue text:

1. *Whether we should require bar codes on prescription drug samples, and the costs and benefits associated with such bar codes.*

N/A for vaccines.

2. *The risks and benefits of including vaccines in a bar code rule.*

PhRMA believes that vaccines should be included under the scope of this proposed rule. However, there is a certain portion of vaccines labels, because of space limitations, will be unable to include a bar code. Therefore, we recommend a specific Datamatrix code.

3. *What terms we should use to describe OTC drugs that should be subject to this bar code requirement.*

N/A for vaccines.

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

In regard to vaccines, the principal reasons for including lot and expiry information would be for vaccine distribution to wholesalers and manufacturers for recall purposes and do not contribute to reducing medical errors.

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

The regulation should refer to compliance with UCC/EAN data format standards and allow the use of both two-dimensional and linear codes. Manufacturers and packagers should not be limited to only linear standards. The relative code sizes and space limitations require the flexibility to use either Datamatrix, RSS or linear codes as required, and as space permits. The error correction capability in Datamatrix will allow it's use and successful data capture on packages where wrinkles and scratches would render other codes unreadable. Even the most space efficient RSS-14 stacked will not fit within the shortest labels and only Datamatrix will allow identification on the smallest label sizes. Please reference the attached business case for inclusion of Datamatrix in the standards.

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

The standard code data structure is seamless to healthcare community using universal scanning devices that are capable of reading both two-dimensional and linear codes. Even though approximately 1% of vaccines are used in a hospital environment, we are committed to provide data we have gathered regarding RSS bar coding and Data Matrix symbologies to our pharmaceutical industry partners.

7. *Whether the rule should adopt a different format (whether that format is a symbology, standard, or other technology).*

This Subcommittee recommends that the rule should <u>not</u> be restricted to just a linear code.

8. *Whether any specific product or class of products should be exempt from a bar code requirement and the reasons why an exemption is considered to be necessary. In addition, how could we create a waiver provision that would minimize the potential for misusing the waiver?*

N/A for vaccines.

9. *Whether the implementation period for a final rule can and should be shortened from 3 years to some other specific time period.*

The Subcommittee agrees with PhRMA and the industry for a 3-year phase-in period.

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

N/A for vaccines.

11. *How the proposed rule might affect hospitals where patients receive blood or blood components, particularly with respect to a hospital's decision to purchase a machine reader (e.g., scanner) that can properly identify the intended recipient of the blood or blood component, the machine readable information encoded on the blood or blood component label and perhaps the linear bar codes appearing on drugs and OTC drugs that are dispensed pursuant to an order and commonly used in the hospital.*

The data structure selected by the Subcommittee is a universal code applicable for blood or blood components and OTC drugs.

12. *Whether any of the alternatives discussed in the economic analysis have merit.*

Contrary to the perceived belief that Data Matrix is costlier to implement than linear bar coding symbologies, our discussions with equipment suppliers and equipment integrators show that this cost difference is now minimal, and on a constant decline. Since Data Matrix Readers can be implemented on a circuit board and have no moving parts, the cost curve is such that Image based readers will in the future achieve lower cost points than current laser based readers. Data Matrix meets the vaccine industry requirements for limited label size and both readers and on-line printers can accommodate current production speeds. It should also be pointed out that over 70% of packaging lines already using machine vision for inspection in the pharmaceutical industry, are already Data Matrix capable, allowing implementation at the lowest cost and in the shortest time.

Best regards,

Aventis Pasteur
Chiron Vaccines
Glaxo Smith Kline
Merck
Wyeth

CC:
Bruce Weniger, M.D., CDC-VISI
John F. Modlin, M.D., Chairman, ACIP
Georges Peter, M.D., Chairman, NVAC

VISI Industry Working Group

Aventis
Chiron
Glaxo Smith Kline
Merck
Novartis
Wyeth

March 11, 2003

Mr. John J. Roberts
Director, Healthcare
Uniform Code Council, Inc.
Princeton Pike Corporate Center
1009 Lenox Drive, Suite 202
Lawrenceville, NJ 08648

Dear Mr. Roberts:

We would like to recommend Uniform Code Council, Inc (UCC) adopt Datamatrix code as one of the UCC data carriers using UCC standard data structure and Application Identifiers (AI). The following is the VISI working group draft Business Case for your review and feedback. Technical data will accompany the final Business Case targeted by the end of April 2003.

1. Barcode Size / Space Efficiency

   Datamatrix is a two-dimensional matrix symbology designed to mark small parts or small items such as electronic chips. So far, it is the most space efficient symbology available.

   In the vaccine business, the common unit of dose packaging is 2/4 ml glass vial or 1 or 1.25 ml glass syringe. Labeling space is at a premium. On the label of these small vials and syringes, the encoding of relevant data with Datamatrix can be accomplished in approximately 1/3 the space of other leading two-dimensional reduced space symbologies without the removal of any legally required label copy.

   Datamatrix is available in a 'square' format but can also be rectangular. Besides it's compact size, this space efficient feature allows Datamatrix to fit, with minimal disturbance to existing print and text layout.

   Datamatrix can be read in any orientation by area imager based technology reader.

2. Favorable for Online Printing and Verification

The pharmaceutical industry requires variable data (lot number and expiry date) to be printed on packaging components (such as a label) during production for proper material control and identification. Therefore, a barcode carrying variable data would need to be printed on the production line. Due to the following features, Datamatrix is favorable for this application.

- Built in redundancy for error correction
  Datamatrix uses error-correction algorithms and is very print quality tolerant.

- Allows high speed online printing and verification
  Reportedly, Datamatrix can be printed at the speeds of as high as 40 **inches**/second (may vary, depending on the length of the label) on the packaging line using thermal transfer print technology. It can be printed with adequate quality for decoding at much greater speeds than any other two-dimensional symbologies.

  It can be decoded by existing vision systems technology, with grading, at higher speeds, up to 3200 labels per minute on label web rewinder applications.

  Human readable information can be printed adjacent to the Datamatrix symbol and verified simultaneously with the verification of the Datamatrix symbol in the same frame capture and decode / inspection.

- Minimal equipment upgrade for vaccine manufacturer is required.
  Every major laser and inkjet manufacturer supports Datamatrix. 75% of currently installed machine vision systems in the pharmaceutical industry are capable of reading Datamatrix. Virtually every major vision system manufacturer with a presence in the industry, with the exception of PPT, already reads Datamatrix. Many of the existing Datamatrix reading systems not only decode the symbol, but they report print scores as well, making it easy to monitor print quality and readability.

  Numerous software packages exist at reasonable cost for incorporation of Datamatrix into Label design on both the PC and MAC platforms.

  In conclusion, online printing and verification with use of Datamatrix will both ease and speed up the adaptation for the use of automatic identification symbologies on pharmaceutical packaging. Most pharmaceutical companies already have both the printing and vision systems in place, to allow this technology to be implemented rapidly and at much lower cost.

3. Low cost scanner available for end user

   Low cost portable readers are available at prices below $600.00 each. The price is still coming down gradually and it is anticipated that the $400 level will be reached within a year.

4. Proven technology

   Datamatrix was first installed in the pharmaceutical industry in 1993 and went operational in 1994. Nine years of use in the industry has qualified Datamatrix as a proven technology.

   Earliest Pharmaceutical Users were Biocraft (TevaUSA), Barr Labs, Warner Lambert, and Rorer. First uses were Outsert Identification, Label Identification and Carton Identification. Wyeth uses Datamatrix on bottle label for version control.

5. Importance of UCC adoption

   It is recognized that the need for a common data structure for identification of pharmaceuticals and medical devices be followed. Ideally, such a data structure would conform to the UCC data structure since it is one of the most widely followed data standards worldwide. It is therefore proposed that Datamatrix be allowed as a suitable symbology (data carrier) with data formatted to follow the exact same data structure as the UCC standards. Failure to allow such an adoption will result in many package forms being unable to carry any means of automatic/electronic data identification and subsequent data capture.

6. Preliminary Recommendations

   Preliminary recommendations for size of Datamatrix code printing, where conventional on-line printing technologies are employed, is for the use of 10 mil minimum, and 13 mil nominal and 15 mil maximum dot size.

   While current handheld readers allow smaller / minimal quiet zones, it is recommended that 2-4 dot quiet zones generally be used around the Datamatrix, so that the oldest of vision systems can successfully find the Datamatrix code on non-oriented product within the field of view. Newer Vision Systems and current Hand Held Readers will permit smaller quiet zones in the one dot range.

Sincerely,

VISI Industry Working Group

cc: Frank Sharkey; Bruce Cohen; Bruce Weniger; FDA