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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:

This letter on the above noted proposed rule is being submitted on behalf of our company
and our many pharmaceutical customers, in the public interest, not to enhance our sales
or reduce our costs. Many of our pharmaceutical and health care provider customers have
written their own responses under separate cover. RDG has also provided technical
assistance to the VISI subcommittee (five of the US drug industry's leading vaccine
manufacturing companies) in it's effort to find a way to add automatic identification
technology to small vaccine vials.

RDG and it's customers support FDA efforts in reducing medication dosing and
transcription errors. For the last two years we have been testing both printing and reading
devices, and technologies, and the use of linear codes versus RSS and Data Matrix and
how they impact product labeling. <u>Our testing and our experience show that the data
structure is what is paramount, and the ability to use both linear and two dimensional
symbologies must be allowed.</u>

Being both a supplier to the end users of this technology and the pharmaceutical
manufacturers themselves, we may be the only company that covers both sides of the
spectrum and therefore feel we are uniquely qualified to understand both side's needs and
problems. We have fully evaluated current technology for both the end users of vaccines
and pharmaceutical manufacturers production lines. I personally have worked with Bar
Code technology since 1975, and have been implementing Bar Code and Vision solutions
on pharmaceutical manufacturer's lines since 1987.

At the FDA Public Meeting on 26 July 2002, I presented our opinions that we feel are
largely in line with those of the VISI subcommittee and PhRMA statement. We believe
that the use of conventional linear bar codes, RSS and Datamatrix should all be
acceptable for primary identification, and specifically through the encoding of the GTIN
number incorporating the NDC number. <u>For most products, the addition of the encoding
of the expiry date and lot data will have minimal beneficial impact</u> and will result in
additional expenses of between $7,500 - $20,000 per manufacturer's line, not including

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validation costs. Such an additional cost will not produce a substantial return on medication error reduction and should not be contemplated except for those products where age and thermal deterioration of the product is such that a breakdown may result in lethality or high risk to the patient.

The stated FDA position in the proposed rule is seriously in error in only considering linear codes. It is apparently based on flawed information from those sources supplying data to the FDA. The use of two dimensional variants of RSS, or the use of Datamatrix must be considered, when both TOTAL COST OF OWNERSHIP, and the ability to encode data on small packages / labels / etc. is contemplated.

It has been implied that the costs to implement two dimensional codes are much higher and that is the reason for their exclusion. There are fatal flaws in this argument.

The true current implementation level for the use of automatic identification technologies, specifically bar code, in the hospital setting does not exceed 1%. Of these, many readers are units from earlier trial programs that are either nearing end of life, or would likely be replaced when bar codes are fully implemented at the end of the three year implementation period.

The basic readers, imager based, are already available from our company and others for prices in the mid $400 range, and these prices will fall into the low $200 range within two years as SOC (System ON Chip) technology is implemented and volumes for imager based readers grow. Some laser based or linear CCD readers for conventional bar codes are less and some cost much more. Therefore, the cost differential is small now and eventually the cost for imager based readers will be less for several simple reasons. Imagers can be produced as circuit boards and realize the benefits of fully automated production. Because lasers utilize moving parts and cannot ever fully realize all the benefits of mass production, they cannot reach the low price / cost points that are eventually obtainable by imager based products. The reality is, that due to the lack of competition and large demand at this point, imager prices are currently artificially higher than they need to be.

TOTAL COST OF OWNERSHIP has been ignored in the arguments put forth in this docket. Laser based readers have moving parts. Therefore, sooner or later, they wear out and the reader or Portable Data Terminal is discarded. Imager based Readers and Portable Data Terminals have no moving parts and no parts to wear out. Therefore, the useful life of Imager based products is greater and when looked at over their lifetime is likely less that that of laser based systems.

TOTAL COST OF OWNERSHIP has been ignored as reflects (Page 12527, N.7) Productivity Losses in Hospital Wards. It had been indicated that a three percent productivity loss would be incurred through the use of this technology. If Imager based readers were used instead of lasers or linear CCD array readers, the ward nurses would not need to orient the reader for the code. Imager based readers do not care about orientation and therefore their use would result in quicker reads and less time lost acquiring data. They could also be used, if so desired, to capture images or signatures that might be important.

<u>In many cases where either mandated text makes larger codes impossible, or where physical size makes the smallest codes desirable, RSS variants and Datamatrix are the only option. As a rule, Datamatrix codes will take up 1/3 the space of the next most space efficient codes. More importantly, Datamatrix can be printed in both square and rectangular formats to take advantage of available space without substantial text relocation.</u>

It has been inferred that Datamatrix is a new technology, that many users do not know how to utilize. RDG first installed this technology on pharmaceutical lines in 1993. It is mature and many reading devices and systems are available for it's use. These same devices also read conventional codes.

All three of the largest manufacturers of domestic Portable Data Terminals, Symbol Technologies, HHP, and Intermec have both Imager and laser / linear array based readers available.

Readers are available in both laser format and imager format that can use the CF (Compact Flash) Slot that is available on many PDAs (Personal Digital Assisstant) to perform data capture on these low cost devices. <u>By utilizing the CF based reading products, obsolescence of the readers themselves could be prevented, and the costs to launch Data Capture Systems in the hospital setting could be minimized.</u>

It should also be pointed out that over 70% of packaging lines already using machine vision for label inspection in the pharmaceutical industry are already Data Matrix capable, allowing manufacturer implementation at the lowest cost, and in the shortest time. This functionality must merely be turned on in their existing systems. Vision systems are not particularly well suited to inspection of linear bar codes, but they do extremely well with Datamatrix. If components must be verified for their code correctness on-line, RDG currently installs very high speed bar code systems for approximately $6,600 each, Datamatrix / 2D RSS systems for less than $10,000 each. If a manufacturer currently has on-line laser based verification for linear codes they are best served by implementing linear codes wherever possible and where space permits. Highest line speeds are possible with linear bar codes since 2000 scan per second lasers can be utilized. The fastest imager based solutions for use with both conventional codes and 2D codes like Datamatrix, can acquire, process and decode 60 images per second. With these reading rates, both conventional linear codes and 2D code based packaging can be run at maximum line rates and no slowdowns are required<u>. The Proposal Document has in our opinion failed to address these costs that must be borne by the manufacturer, unless of course the readability of these codes is never to be verified.</u>

If secondary information must be encoded for a limited set of products, the highest on-line print speeds are possible with Datamatrix due to it's relative tolerance to print degradation versus linear codes and RSS.

Please see the last page of this submission for a comparison of codes.

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.*

No benefit for bar coding of samples is seen except for the manufacturer's them selves who need to monitor their disbursement and who could realize gains by automating this process.

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

Vaccines should be included under the scope of this proposed rule. However, many vaccine labels, because of space limitations, will be unable to include a linear bar code. Therefore, we recommend Datamatrix code.

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

No Suggestion.

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

The principal reasons for including lot and expiry information would be for distribution to wholesalers and manufacturers for recall purposes and do not contribute to reducing medical errors, with the exception of products which are altered by age or thermal decomposition / modification.

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.

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 imager based scanning devices that are capable of reading both two-dimensional and linear codes.

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

It is recommended that the rule should not be restricted to just a linear code. Datamatrix and 2 Dimensional variants of RSS are both more space efficient and in the case of real world use, the error correction built into Datamatrix will allow it to be read if as much as 25% of the code has been altered or destroyed. A mere line through a linear barcode will render it useless and unreadable.

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?*

No products should be excluded.

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

A 3-year phase-in period is suitable and should not be extended. If Datamatrix were allowed, many manufacturers could accomplish this task in a much shorter time period due to their ability to easily fit this code within their existing text as well as the fact that over 70% of the vision systems that they already have on their lines already have the capability to read Datamatrix codes.

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.*

No Comment.

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 GTIN data structure incorporating NDC 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,

Robert W. Rack

President

Rack Design Group Inc. / BarCodeAmerica.com

RSS - Data Matrix Comparison

Symbols with 14 digit GTIN

RSS	Data Matrix	14 digit Code 128
(01) 0 00 12345 67890 5 RSS Stacked .008	(01) 0 00 12345 67890 5 Data Matrix .008	(01) 0 00 12345 67890 5 UCC/EAN-128 .008
(01) 0 00 12345 67890 5 RSS Stacked .010	(01) 0 00 12345 67890 5 Data Matrix .010	(01) 0 00 12345 67890 5 UCC/EAN-128 .010
(01) 0 00 12345 67890 5 RSS Stacked .012	(01) 1 12 34567 89012 5 Data Matrix .012	(01) 0 00 12345 67890 5 UCC/EAN-128 .012
(01) 0 00 12345 67890 5 RSS Limited .012	(01) 1 12 34567 89012 5 Data Matrix .014	

Symbols with Date and Lot Code

(01) 0 00 12345 67890 5

RSS Limited Composite .010
With DATE: 99/12/31
Lot: ABC123DEF456

(01) 1 12 34567 89012 5

Data Matrix .014
With DATE: 99/12/31
Lot: ABC123DEF456

(01)00012345678905(17)991231(10)ABC123DEF456

UCC/EAN-128 .014