

**Robert Rack**

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**From:** Robert Rack [rrack@rdgguys.com]  
**Sent:** Friday, July 12, 2002 6:43 AM  
**To:** grossm@cder.fda.gov  
**Subject:** Summary of Presentation materials for July 26 meeting on Bar Code Labeling Requirements



FDA 7-26-02 Bar Code

Meeting P...

Dear Ms. Gross:

Attached you will find an extended summary of the issues I would like to address at this meeting. Hopefully I will be given the opportunity to do so since I think my positions are technically accurate, I understand the issues from all sides, and from a business standpoint I am perfectly neutral. Regrettably, I know that several of the people who told me that they intended to speak, are not.

I look forward to hearing from you and meeting you.

Sincerely,

Robert W. Rack  
President  
Rack Design Group, Inc. / BarCodeAmerica.com

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**Robert Rack**

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**From:** Robert Rack [rack@rdgguy.com]  
**Sent:** Thursday, July 11, 2002 3:48 PM  
**To:** grossm@cder.fda.gov  
**Subject:** Speaking at the July 26 Meeting on Bar Code Label Requirements

Dear Ms. Gross:

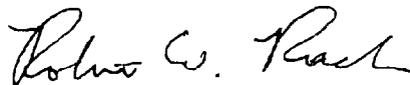
I am writing to inform you that I would like to speak at this meeting. An outline of my presentation will be forwarded on Friday. I presume that is within the deadline for submission. I would also appreciate it if you could give me an idea of how much time may be available to make a presentation.

I have a unique perspective on the issues at hand. My company is a solutions provider to the pharmaceutical industry providing primarily packaging floor solutions, printers, bar code reading systems, vision systems. In addition I understand and have delivered systems for product control throughout the distribution chain. But between 1987 and 1992 I was one of the people working with the PMA that developed the bar code labeling standards and did the actual lab testing that determined what was and was not printable, and what were the optimum ways to accomplish the task, and in so doing created many of the labeling standards that exist to this day. During that period, I was working for Bristol-Myers Squibb. At this time my company also runs one of the largest On-Line stores for Automatic Identification equipment, so ultimately we deliver the systems that the end users will require to read these codes. Whether RSS or Datamatrix is selected, readers are required, and therefore unlike many others, we can provide an unbiased technical reasoning for adoption of a particular technology, rather than that we have only one technology to sell. Frankly I merely want to see it done right this time because I believe this to be the last opportunity to get it right.

I believe that the tasks at hand can be accomplished, but am concerned that a one size fits all approach is being employed, when with the use of the proper reading technologies, either RSS or Datamatrix can be employed. Their are obvious instances where RSS does not fit on the smallest packages. I also believe that all the information that has been requested can be fit, (including lot & date codes, and package ID serialization) and that by employing the proper methodology we can not only reduce the instances of medical errors, but also eliminate the growing product counterfeiting problem. I can also demonstrate cost effectiveness for these technologies. Costs that have been cited for implementation at the point of use are far too high and there are novel ways to reduce the costs at the point of use. I am also concerned that the technology chosen must be able to produce the quality of codes that can be printed with on-line real time methods, allows real world high speed reading verification on line speeds of up to 450 bottles per minute, and whose quality can be maintained in real packaging conditions.

My ability to address the technical and cost issues will be determined by the time that is allotted to me. I am concerned about some of the misinformation that I have seen that has been spread by some of the "experts", particularly as regards the use and adaptation of Datamatrix. I am equally concerned that while the pharmaceutical industry has expressed concerns about the issues associated with adaptation of some of these codes, that this not be turned into a long period for adaptation since the technologies to implement a solution do exist, and are available today if the right technical selections are made. I also believe that we should look forward to how technologies can be used to insure that the efficacy of the drugs dispensed are adequate, and that the drugs have not been aged beyond their usefulness by either age or thermal abuse. In addition, I feel that this is the time to put in place the standards that will reduce counterfeiting, and that this period of change is the best time to accomplish that task. It may never come again.

Robert W. Rack  
President  
Rack Design Group, Inc. / BarCodeAmerica.com  
973-377-8182 Office  
201-220-1092 Cell



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## ***Which Medical products should carry a bar code?***

All prescription drugs, blood products, and medical devices that will be left within the body should be bar coded. All other products that have a likelihood of some patients having allergic reactions should also be bar coded. All implanted devices must be identified with a unique sequential serialized code.

## ***What information should be contained within the bar code?***

The bar code should identify the product. For a drug this means the NDC number. For most products the code should also contain expiry date and lot code information and a unique sequential serial number at the end of the code, space permitting. By using the appropriate density data matrix code, there is no product that could not have all this information encoded despite it's size. A 4 character alphanumeric serial number at the end of the code would allow the identification of 1,679,616 unique items within a lot making absolute traceability possible.

## ***Which symbology should be selected?***

Both the RSS and datamatrix codes can and should be utilized. It must be recognized that datamatrix will allow smaller codes to be created within areas of labels and product identification than is possible with RSS. It is also possible with datamatrix to create the extremely small codes that might be required on implantable devices. On many labels RSS-Limited or datamatrix could be used with equal effectiveness. Both RSS and datamatrix should be allowed. This requires the adaptation of imager based reading technologies rather than the use of lasers in the future. The use of imagers will permit the reading of both symbology types, image capture, signature capture, and it will also create more reliable reading systems that have no moving parts to wear out. The selection of technology will be limited by the real estate available for the product marking, and whether or not high speed reading and verification systems exist that can verify the quality of those printed codes at production speeds. At very high production speeds those systems exist today for datamatrix. For RSS codes, those high speed readers should be available within several months. That makes the next critical question the issue of whether or not the technology exists for creating adequate quality codes with the on-line printing methods available. At this time, very high speed print capability exists for both static and sequential datamatrix codes. Currently, medium speed static RSS codes are possible with on-line printing methods. For medical devices, there are many laser technologies that can currently print the smallest datamatrix codes but none that are currently printing extremely small RSS codes.

## ***Practical limits of the symbologies.***

The practical limits of the symbologies are determined by the printing method to be employed and the reading devices available at the point of use. It has been commonly said that the limit for RSS codes is 6.7 mil on labeling. That is true for excellent quality print. However past testing of the printing methods used in the real world in the pharmaceutical industry show that printing and maintaining

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quality below 8 mil is problematic. If on-line printing methods are employed such as high speed thermal transfer, the 300 dpi limit of these print heads may make 10 mil dot size what is the most maintainable in the real world. Extremely large messages could be created with either RSS or datamatrix codes should they be required and if the printing methods are adequate.

## ***How are bar codes used now and how should they be used in the future?***

At this time even the existing bar codes are underutilized. They are primarily used at present to assure packaging component verification on the pharmaceutical packaging line. Adaptation of automated reading technology must be implemented at the point of use / dispensing for the advantages inherent in using automatic data capture and verification to be realized. If such adaptation is not implemented, this additional identification will be largely wasted except for the ability to perform product recalls and implement anti-counterfeiting schemes.

## ***How should medical devices be bar coded?***

Due to their small physical size and the way in which they are used, most medical devices will be identified by directly etching the code into the product. This may be accomplished chemically or through the use of lasers. For the smallest of these devices only datamatrix is practical and very high density datamatrix readers may be required. For many medical devices such as orthopedic implants (knees, hips, etc.) these codes can be added on early in the production cycle to insure that the product goes through each production step required of it. Unfortunately the very nature of these products is that to the human eye there may be no difference if a critical production step has been missed (multiple heat treating cycles for example) and if the paperwork associated with it is incorrect. By having a unique ID on each product at the production stage that is next in the cycle, the device can be read and it's movement through that cycle recorded and verified.

## ***Costs and technical issues for consideration?***

For the pharmaceutical company datamatrix could be implemented now and present production speeds could be maintained on even the highest speed lines. Datamatrix could be more easily incorporated within limited label copy areas. On-line printing of RSS may require the use of dual printers at the highest production rates to achieve the requisite quality. In reality, poorer physical quality datamatrix codes are readable by existing technology than is the case for RSS. If only linear versions of RSS were to be used, the cost to end users may be less for RSS codes. However if all the information that is desired to be passed to the end user is implemented, there is no real difference in the reader costs for the end user. At the point of production many pharmaceutical companies have already implemented machine vision technology to assure readability of their printed expiry and lot codes. Most of the systems in place are also capable of reading datamatrix. None read RSS at this time and it's addition may require both hardware and software upgrades.

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## ***Production Issues***

At this time it would be easier for the manufacturers to implement datamatrix. In the area of label design / redesign most of their existing packages support the addition of datamatrix codes. For those designing in the Windows environment, many software packages also support RSS codes. Unfortunately, for those many art departments that design in the MAC environment, at this time only one relatively costly design package is available to implement RSS codes.

As regards the production line itself, matrix codes and quality can be maintained and monitored at higher speeds and lower costs with datamatrix than with RSS at this time. As more RSS capability is added by equipment manufacturers (printers & readers) this disparity will be reduced but will never be completely eliminated due to the fact that poorer quality matrix codes will always be more readable than RSS codes, raising production costs by increasing rejects due to code readability.

## ***Expected Benefits***

Besides assuring that the correct drug is dispensed, the use of automatic data capture can streamline the recording and accounting functions. It can be used to reduce counterfeiting. If patient IDs were created that identified any allergies at the time of admission, reading of those codes before dispensing could prevent potential allergic reactions. If imager based readers are employed, signature images could be captured and true accountability established.

## ***Controlling Efficacy***

The addition of expiry dating and it's automatic capture as a check could be used to assure that out of date product is not dispensed. It can also be used via database to assure that the lot is an acceptable one that has not been subject to recall.

## ***Preventing Counterfeiting***

Recently product counterfeiting has become more of an issue. While many techniques can be employed that will reduce the incidences of counterfeiting (IR, UV, Product Unique Chemically Activated Indicators, Holograms, etc.), most of these can eventually be counterfeited as well. Therefore, the only way to assure that a particular package or item is unique and has not been duplicated, ultimately is to read it's unique ID and query a database over the web to determine if that package has been used before. If it has, then it should be flagged and the location at which the number has been previously used identified and an investigation initiated. Only by the use of such technology will the counterfeiting gap ever be totally closed. Handheld devices with the imaging technologies we have suggested as well as the Wireless links to access networks or the web can be had for approximately \$2,400. These devices could not only perform these functions, they could update all relevant databases (hospital, care provider, insurance) in real time, improving performance and reducing costs. If access to live databases is not to be considered, the use of a check digit encoding scheme that is unique to each manufacturer and identified in his product ID and calculated

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and dependent upon the 4 character sequential serial number that is proposed for the end of the code, should be employed to assure that the product is not counterfeit.

## ***Small Package / Label Marking Key Issues:***

### **On-line Printing:**

While 6.7 mil print widths have been specified as the lower limit for RSS-14, real world experience indicates that most vendors and end users have problems maintaining print quality consistently below 8 mil print width. On very small labels, this will present problems with the vertical registration on the RSS-14 codes. Datamatrix has room to spare.

It is recommended that where space is available, at least 8 mil RSS-14 Limited is used.

Since it is much more space efficient, 10 mil Datamatrix could readily be used and is recommended.

Using wider codes (dot sizes) with both codes allows lower resolution reading devices to be used that have more focal depth of field ( a wider sweet spot of successful reading range).

At this time Datamatrix printing technology can be added to existing labelers at the cost of about \$11-13,000 per line installed and acceptable results achieved. Datamatrix print verification could be added for about \$13,000 per line complete with ANSI grading of the data matrix print quality in real time on every label.

At small vial line speeds (400-450 / minute), both high speed thermal transfer printing technologies, and continuous ink jet systems exist that could print the Datamatrix codes required at readable quality levels. This can be achieved with RSS-14 at lower speeds with thermal transfer print technology. The width of the RSS-14 limited code would preclude the use of Continuous Ink Jet technology at these line speeds and the stitching together of multiple heads at these speeds would not result in quality codes in the required orientation. Printing date and lot codes adjacent to the Datamatrix would optimize performance.

### **Datamatrix and RSS-14 Reading Devices (Handhelds):**

Readers from at least 5 different manufacturers exist that can decode both RSS-14 and Datamatrix symbologies. Cost of these handheld devices begin at about \$600.

Prices for a complete handheld batch data collection unit including the requisite accessories would be about \$1,200 with charger and communications cradle. Costs climb from there up to the \$2,500 range for the units complete with wireless communications, 2D imager, touch-screens, 32MB of Memory, and capability to connect to the internet.

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With the dramatic drop in prices for imagers due to the adoption of CMOS imager technology and peripheral circuitry, it is anticipated that the cost of imagers will drop below the cost of lasers within 12 months and this downward trend on prices will continue due to the manufacturing efficiencies and the removal of all moving parts. Additionally, the use of imagers will allow for image and handwriting capture, increasing overall system security.

## **Datamatrix and RSS-14 High Speed On-Line Reading Devices:**

The ability to perform high speed on-line machine vision reading of RSS-14 codes on line at the 400-450 vial per minute rates discussed at this time does not yet exist. Prototypes have been demonstrated that are capable of reading the code and several new products with this code reading capability should be released within the next 90 days.

High speed on-line data matrix readers from six different manufacturers are available with basic prices for the reader hardware starting at about \$3,200 before any peripheral control electronics and controls are added.

We have added high speed validated installed data matrix systems to pharmaceutical packaging lines from prices starting at \$8,000 cost installed / turn-key on end user lines. We anticipate similar prices for RSS-14 technology about two years from now. The initial technology required for high speed RSS-14 can be expected to cost about \$16,000 and up. End users can anticipate the cost for adding such reading capability for high speed on-line use to range from \$8,000 to \$25,000 for high speed web rewinder applications where speeds of over 2,000 labels per minute have been reached, complete with ANSI grading of Datamatrix codes.

## **Off-Line Print Quality Verification:**

The cost of the only Print Quality Verifier in existence for RSS-14 is \$6,995. A similar cost is required for Datamatrix Print Quality Verifiers, although some can be had for as little as \$4,995. At this time no one unit can currently perform print quality verification on both RSS-14 and Datamatrix although such a unit is planned for release by the end of this year.

## **Future Considerations:**

To totally close both the existing product monitoring and recording gap, as well as the growing problem of counterfeit product, it is recommended that the use of serialized Datamatrix or RSS-14 codes be considered. In addition to assorted chemical authentication materials, UV marks, IR marks, and other schemes (Holograms, etc.), it is apparent that only by going to a product look-up of a unique serial number can the user be assured that it is unique and has not been used before. By appending a 4 digit alphanumeric code at the end of these symbols, 1,679,616 different unique packages could be associated with a particular lot and authentication would be possible. If a number has been used elsewhere, one is not real product.

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If a serialized code is to be added, at this point it could only be accomplished at high line speeds with Datamatrix. Datamatrix has been integrated into both thermal transfer and inkjet printer controller engine technologies so that it could be re-imaged and serialized on the fly, internal to the printer engine controllers, at these speeds. Most RSS-14 codes are currently image maps that are being downloaded from the host controller and could not be re-imaged remotely at these line rates.

## About the author:

Robert W. Rack is president of Rack Design Group, Inc. and BarCodeAmerica.com. Over the last 10 years his company has installed several hundred machine vision systems and over a thousand bar code reading systems into pharmaceutical applications. His company provides both turnkey systems to manufacturers as well as reading, printing, and data capture systems for the end user environment. Previous to this Mr. Rack worked for 6 years at Bristol-Myers Squibb and did much of the testing that established present day package identification, labeling, and printing standards. Therefore Mr. Rack understands the needs of both the end users as well as the constraints and problems of pharmaceutical manufacturers in adopting these technologies.

Mr. Rack can be reached at 973-377-8182. Faxes should be directed to 973-377-8183.

Correspondence should be addressed to:  
RDG / BarCodeAmerica.com  
PO Box 506  
Madison, NJ 07940

July 12, 2002

FAX TRANSMISSION – 4 PAGES

To: Mary C. Gross  
Office of Drug Safety  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane, Room 15B-32  
(301) 827-3193  
(301) 443-9664 (fax)

From: Diane Goyette  
Director, Regulatory Affairs  
Healthcare Distribution Management Association

Subject: Request to Speak at FDA July 26 meeting on bar code labeling

I have attached a request to have Robert Schwartz, HDMA Chairman of the Board, represent HDMA members at the July 26 public meeting on bar code issues. I also e-mailed this information to you late yesterday Thank you.

July 11, 2002

Mary C. Gross  
Office of Drug Safety  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane, room 15B-32  
Rockville, Maryland 20857

Dear Ms. Gross:

I am writing on behalf of the Healthcare Distribution Management Association (HDMA) to request an opportunity for presentation of member views at the July 26 public meeting on the development of regulations on bar code labeling for human drug products. HDMA is the national trade association representing healthcare product distribution in the United States. HDMA members operate over 260 distribution centers nationwide, distributing healthcare products and innovative services to approximately 118,500 pharmacy settings including independent, chain, hospital, mail order pharmacies and mass merchandisers, food stores, long-term care, home health facilities, clinics and HMOs

Robert Schwartz, the Barnes Division President of the H.D. Smith Wholesale Drug Company, and current Chairman of the Board of HDMA, would be pleased to present an overview of the Association, discuss the current state of the industry's acceptance of bar codes and the technology available to support this initiative. Mr. Schwartz would also highlight the benefits of bar coding and present industry statistics related to bar code usage in the manufacturer, distributor, and hospital customer settings. Finally, he would provide expert insights into how the changes to the identification systems FDA is considering could impact the healthcare supply chain.

HDMA has traditionally been a strong supporter of efforts to reduce medical errors. We have been an active participant in the National Coordinating Council for Medication Error Rates and Prevention (NCCMERP) since 2000. HDMA has also been a pioneer in promoting the usage of bar code standards in the healthcare industry since the early 1990's. We have worked collaboratively with the Health Industry Business Communications Council (HIBCC) and the Uniform Code Council (UCC) to develop voluntary guidelines for the industry. Additionally, we have developed our own industry positions and guidelines on the usage of bar codes.

HDMA members are very significant stakeholders and should be part of any discussion about healthcare product bar code labeling requirements. We would very much appreciate the opportunity to provide information and present our views at the July 26 public meeting on these issues. We look forward to continuing to work in cooperation with NCCMERP, FDA and the healthcare community to find solutions that will improve patient safety without disrupting the flow of products through the healthcare system. Attached, please find a brief summary of our proposed presentation. Thank you for your considering our request.

Sincerely,



Diane Goyette, RPh, JD  
Director, Regulatory Affairs