



4 Cain Drive
Brentwood, NY 11717
(631)952-3747
fax (631)952-3595
info@webscaninc.com
www.webscaninc.com

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Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

To Whom It May Concern:

I am writing to comment on the proposed Bar Code Rule for Hospital Unit Dose pharmaceuticals.

Here is a brief outline of the remainder of this letter:

1. Thank you for the proposal
2. Please clarify what is meant by linear bar code with respect to multi-row, "line scannable" bar codes.
3. Please expand on Bar Code Print Quality
4. Some comments on the UCC system
5. Some thoughts on lot and expiration
6. Information on the commenter

Each of these points will be discussed in the following few pages. Thank you for reading these comments. If I can be of any assistance please feel free to contact me.

Sincerely,

Glenn Spitz
President

Email: gspitz@webscaninc.com
Phone: (631)952-3747

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1. Thank You For the Proposal

I would like to express the fact that the proposed rule was very clear and well thought out, and your reasoning behind it was well supported. I personally support the idea for the rule and wish to see it carried out as soon as possible to greatest effect. The comments in this letter are in support of the proposal and only offer some thoughts on the alternatives that may still be in consideration.

2. Please Clarify What is Meant by Linear Bar Code

First of all, I think we all would understand that a Code 128 bar code is an example of a linear bar code. So is a UPC symbol. So is an RSS14 Limited symbol, or an RSS14 symbol. However, what about an RSS14 stacked?

RSS14 stacked is essentially the same thing as RSS14, except that it is printed in two rows in order to make it narrower at the expense of height. The reason that this can be done is that the symbology is designed in such a way that the parts of RSS14 can be decoded independently of each other. The structure of an RSS14 symbol is like this:

Data	Left Finder	Data	Data	Right Finder	Data
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The RSS14 symbol is decoded by locating the finder patterns and decoding the data characters adjacent to them. (Each element pictured above consists of 8 bars and spaces).

The same data can be laid out like this in an RSS14 Stacked symbol:

Data	Left Finder	Data
Data	Right Finder	Data

In both illustrations I have left out the few guard bars that exist at the left and right ends of the whole structure.

Since the data is always located by the adjacent finder patterns, a scanner can easily decode the whole message in a stacked RSS14 symbol after they are all decoded.

I do not know of a scanner that can read RSS but cannot do this reconstruction. In fact, a typical scanner will not even "know" if the symbol is laid out in a single row or in two rows. I hope you get input from Scanner manufacturers on this point.

It is important to note that even single line scanners can easily and quickly read this type of symbol.

This is what I would consider a symbology that can be read by a line scanner, or in other words this is a "line scannable" symbology.

Therefore, please clarify what is meant by linear bar code. Do you mean to include the possibility of RSS14 stacked?

I recommend that RSS14 Stacked should be allowed.

I totally subscribe to your reasoning that the lowest cost option should be left open for hospitals, and that lowest cost option is a single line scanner, be it a single line CCD or single line laser.

3. Please Expand on Bar Code Print Quality

In the proposal, you mention that Bar Code Quality is well understood in the industry, and that is true. This industry has a history of very quantifiable measures on bar code quality and robust technical standards. These standards have in part been responsible for the success of bar codes in the retail industry. The standards enable a whole industry to function as one "closed" application by effectively defining the roles and responsibility of each participant, whether you are a scanner manufacturer, a consumer goods manufacturer, or a printer of packaging material that contains a bar code.

Special instruments, called Bar Code Verifiers, have been produced by several manufacturers. These instruments evaluate bar code print quality against an objective standard and report the quality level of a bar code sample. In fact instruments have been made to do this on-line and report on the quality of every single bar code printed. Some on-line instruments produce a high sampling rate, but not 100% when more than one bar code is printed at the same time, as is common for blister packs for example.

For ease of communication, the quality of a bar code is expressed as a grade on a scale of 0.0 to 4.0, with 4.0 being the highest grade. For further clarification, letter grades have been associated with the numerical scale, ranging from F (lowest grade) to A (highest grade). It is generally accepted that a C grade or better is a passing grade.

A passing grade (C) means that a given bar code should be scannable, though perhaps not as easily or quickly as a B or A grade symbol. A symbol with a D grade may be scannable by some scanners, but not necessarily by all scanners

and maybe not on the first attempt. Same goes for F grade symbols, only with even less performance.

The reason bar code quality is important is that for the system to function, the bar code must be minimally legible to a typical scanner. Clearly, if someone puts a blot of ink on a label and claims that it is a bar code, that does not meet the intent of the proposed rule. The rule should therefore mandate a minimal passing grade.

I recommend that the rule be explicit in making the passing grade a C or better (on the numerical scale greater than 1.5). Fortunately there are international standards that apply, ISO15415 and ISO15416.

The issue of sampling versus 100% inspection seems to come up frequently surrounding the issue of bar code quality. On the one hand, printing processes tend to degrade over time but slowly. This would support the argument that a sampling process would suffice. However, there is always the possibility that a defect in the material that is being imprinted could show up as an imperfection in the printed matter.

I think it is important to sample frequently, at least more frequently than the period of time in which the printing process is known to remain consistent. As for the odd imperfections in the stock material, we should realize that the bar codes being used are generally tolerant of some imperfections and we should allow for that in our acceptable inspection regimens. 100% inspection may be more costly than the benefit, but periodic inspection to a minimum C grade is critical.

A further note, it is common for a printing process to produce several images in parallel. For example, on a blister pack line, some 40 or more individual unit doses may be printed with a bar code using a single plate that simply has the same images repeated across its width and length. Each of these individual spots must be checked periodically. It is important that a system be used to ensure that each individual spot is checked. I would rather check each blister 1% of the time than 39 out of 40 blisters 100% of the time while leaving one blister never being checked.

4. Some Comments on the UCC System

The UCC, more than any other organization I am familiar with, has established the infrastructure to make the voluntary standards flourish. Specifically, the UCC has created Calibrated Conformance Standards for U.P.C. and just recently for RSS and UCC/EAN-128 as well. These conformance standards are cards that have nearly perfect symbols with very well controlled imperfections engineered into them. These cards are used to prove that bar code verifiers work correctly

and are being used correctly. Because of these calibrated conformance standards, bar code verifiers from a variety of manufacturers can produce comparable results. The UCC has invested in engineering these symbols and in producing the metrology capable of calibrating these standards and making them traceable to NIST.

No such conformance standards exist for Data Matrix or any matrix symbology.

The UCC system is item number centric. The design of the Composite Symbology clearly makes it easier and therefore cheaper to read the item number when that is all the user needs. I think that it is a clever idea to separate the item number from any additional information such as lot number and expiration date, and keep the item number in an easy to read linear, or line scannable, bar code.

The UCC also has specifications on Symbol Quality, including the 'C' or better grade for passing.

5. Some Thoughts on Lot and Expiration

There is value to having the lot and expiration date in a bar code that could be used, but optionally, by hospitals and pharmacies and anyone in the supply chain. The traceability and aid in recall would be great benefits. If a hospital could capture the lot number of every drug given, and then a recall is made, they could easily determine what patients were administered the recalled drug. I am not in any way knowledgeable about the practice in the medical profession and so my "analysis" ends there. However, I want to point out that it is practically no more costly to imprint a bar code that includes lot and expiration date than it is to imprint only the NDC number. The purpose of mandating the lot and expiration would be so the hospitals could be assured of a return on their investment if they were to invest in a system to capture it.

However, there are certain problems that would arise if the lot and expiration date were mandatory. First, of all, there are some who claim that the information would not all fit on the smallest of unit doses. Some of these claim that the only way they can include this information is with Data Matrix which is more space efficient than the UCC Composite Symbology. However, others claim that RSS composite symbology can in fact fit in the label space available. It is possible that since more label space would be required for the bar code, less room would be available for other printed information. I have not analyzed the merits of these claims. In fact only the manufacturers know the exact sizes of all of the labels they use. You will surely receive many comments from others on this issue.

Data Matrix is significantly smaller -- about 2:1 ratio in size. However, the small size is due to the minimum of structure within the symbol that enables reading equipment to recognize the symbol. RSS contains more structure to enable each line scan to decode what is scanned on that line. This structure takes more room. It is my firm belief that scanners that can read line scannable symbologies must be less expensive than 2D imagers.

RSS and Composite Symbology is line scannable -- in fact very similar to linear bar codes. RSS characters, whether in the primary component which contains only the NDC number, or the Composite Component which can contain the Lot and Expiration are self clocking. This means that a fixed and known number of "modules" is used for a fixed number of elements (bars and spaces). Within the Composite Component, the row number is encoded on every row which enables information to be extracted from each line scan independent of any other scans. This structure requires more space than what is used in Data Matrix.

There is also the possibility that if no requirement is made for the supplemental information then each company who chooses to include such information may do so using incompatible symbologies, leaving the hospitals with little benefit. In order to maximize the probability that hospitals could use the supplemental information, a mandate should specify which type of bar code it should be if it is there at all. To maximize compatibility with the UCC system and reading equipment that might be purchased by hospitals, I recommend that the UCC system (Composite Symbology) be mandated for the lot and expiration.

If on the other hand, Data Matrix is allowed for supplemental information, I would then recommend that the primary item number (NDC number) should still be imprinted in a linear bar code. Otherwise, the item number (NDC number) could only be used by reading the 2D bar code.

6. Information on the Commenter

This letter is written by Glenn Spitz, the president of Webscan, Inc. a manufacturer specializing in bar code verifiers since its founding in 1995. Webscan produces bar code verifiers for linear bar codes, RSS14 and Composite Symbology and Data Matrix.

Prior founding Websca, I worked at Symbol Technologies, which is a leading manufacturer of bar code readers. At Symbol I was in charge of Decode Algorithm Development. I hold a Masters Degree in Electrical Engineering from Columbia University and a Bachelors Degree in Electrical Engineering from SUNY Stony Brook.

I have been personally involved in standards development with ISO, AIM and

UCC since the early 1990's. I am a member of the UCC's Global Symbology Committee and a member of the U.S. TAG which works on the development of ISO specifications. However, these comments and opinions are my own and do not necessary reflect those of other members of the committees of which I am but one member.

I am intimately familiar with the design of the RSS bar code family and Data Matrix. I like to think that I am impartial with respect to the debate between proponents of RSS and proponents of Data Matrix. I believe that usually these two groups are not completely truthful in their arguments. In short, the two symbologies make differing tradeoffs between overall size on the one hand, and the ease with which (and correspondingly cost) to scan.

I thank you for reading my comments and would be glad to offer any clarification or other assistance you might deem necessary or helpful.