Commendation and Comments
Related to Proposed FDA Rule
Bar Code Label Requirement For Human Drug Products and Blood
Docket No 02N-0204

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COMMENDATION

The FDA is to be highly commended for both the proposed regulation and the process leading to it.

It is obvious that you have listened carefully and without bias. It is impressive how you were able to sort through diverse testimony offered at the July 2002 hearing, as well as from subsequent submissions and lobbying. You succeeded at separating the wheat from the chaff.

I am convinced that no one of us is an expert on this subject. Rather each of us holds a few pieces to the puzzle of a great picture that needs to come together. You have done a great job positioning the pieces we've thrown at you. The word **leadership** comes to mind.

You all have my highest respect for the way you have conducted business on behalf of the American pubic and with me personally.

With gratitude and high regard,

Mark Neuenschwander

COMMENTS

ONE: No exemptions

I believe that you are wise to make no exemptions on barcode labeling.

1) While you are being pressured by some to grant exceptions, particularly for 5mL vials, the fact is 5mL vials are being successfully barcode labeled at present.
2) It is noteworthy that liquid medications are more typically related to errors that do harm than are oral solids.
3) Granting any exceptions would indeed militate against the value we all seek from this regulation. I believe you are spot on in suggesting it would only "consume agency resources as some individual or firms may be tempted to submit exemption requests notwithstanding their ability to comply with a particular regulatory requirement." (p. 50) I admire your kind understatement.

COMMENTS

TWO: Declining to Require Lot Number and Expiration Date

It is right that you decline to require these.

1) To do so would make barcode labeling even more complex--so complex that I fear it would only serve to discourage manufacturers and packagers from packaging in single unit packages. This would take us in the opposite direction of the regulations good intent.
2) We have reason to believe that the market itself will in fact drive the inclusion of these data elements (which, incidentally, the regulation does not prohibit)

   Note: You were logically on target in arguing that the market was not going to drive barcode labeling. But the same logic does not apply to lot number and expiration date. The *great impasse* found manufacturers saying, Why should we apply barcodes if hospitals don't have point of care scanning systems in place? while the hospitals said, Why would we adopt point of care scanning systems if manufacturers don't include barcodes on their labels? But no one is going to say, Why should we adopt point of care systems when we can't scan lot number and expiration date. The all-or-none proposition does not apply to expiration dates and lot numbers they way it did to barcodes. There was no value for a hospital to pay more for barcode labels until they had scanners. But there is value to the barcode scanning hospital to pay more for barcodes that include lot and expiration--no matter how many or few drugs include them. We can expect scanning hospitals to buy from the manufacturer/labeler that offers the value added of the additional data. Indeed, now that the manufacturer/labelers have to apply barcodes, it appears as though some are seeing the competitive advantage of including lot and expiration (Pfizer, Baxter, etc).

3) In any instance, lot and expiration are still required in human readable print, which is as good as we have had it, no worse.

COMMENTS

THREE: Limiting the barcode to linear barcodes of the UCC/EAN standard

I consider you brilliant on this point, even though I was one of those pressing for "machine readable codes that can be easily read by current scanning technologies." Thank you for listening to everyone on this and seeing what I could not see. Your logic was impeccable and I need not rehearse it. However, I would like to add some thoughts which I think are germane to the discussion.

1) It will be another five years before RFID chips start showing up on individual grocery items (if ever they do). It will be even longer before they show up on manufacturer "unit dose" medication packages.
2) If we think manufacturers are resistant to the current proposed regulations, what could we expect if we were to require RFID. Even five years from now the retooling for this would require dramatic change and cost.
3) As for other multi-dimensional images, they will have their place in proprietary and closed systems (e.g. FedEx, UPS, etc.) but they will never appear universally on products. If ever barcodes are *universally* replaced, the market will jump over visual line of sight symbols (no matter how sexy they may be) in favor of proximity activated electronic product codes (i.e. RFID).
4) Even if RFID were to become a *universal* electronic product code (ePC), it would only happen over many years and the transition would probably be slower than the transition from the cassette tape to the CD. The CD has been out for a very long time, but until everyone has CD players, cassettes are still being made. Likewise, until everyone has RFID scanners, even if products have RFID chips, they will also still need to have barcodes. We might be talking decades.

Note: It appears to me that there is some confusion of nomenclature related to the words symbology and standard. My understanding is that the UCC and HIBICC "standards" have nothing to do with symbologies. Rather what has been standardized is the order of the data sets. This is similar to syntax in a language. In contrast, "symbologies" are akin to language. For example, HIBICC utilizes RSS symbologies that order the data in HIBICC format.

It should be noted that RSS (Reduced Space Symbology) is a symbology that is patented by the Uniform Code Council.

This makes me question what the proposed regulation means by UCC linear codes. Does this allow for HIBICC formatted information that is presented in

RSS? In other words does the UCC qualifier apply to both symbology and data formatting? I believe this needs to be clarified.

Note: I am in hearty agreement that you should limit the barcodes to linear. But, it appears to me that there is another bit of confusion over terms here as well. Simple linear barcodes can be read with conventional laser scanners, while multi-dimensional codes require image readers. However, there is confusion over the composite barcode that needs to be clarified.

Sometimes the UCC refers to composite codes as two-dimensional. However, when pressed they agree with me that they are really made up of several thinly stacked linear codes. Thus they may be read with lasers readers as can simple barcodes. Granted this will require older scanners to be replaced and more recent scanners to be software upgraded. But, they are, nevertheless linear codes, as opposed to data-matrix and other images.

Therefore, I am hopeful that in the FDA will consider composite codes as linear codes. I would be happy to discuss this further and would encourage a good in-depth quizzing of the UCC on this matter.

Note: There are not enough scanners in hospitals today be concerned about hospitals having to upgrade to state of the art linear barcode hardware and software. First of all, of the few that do have them, they have very few scanners. Second, of those that have them, a significant portion is software upgradeable. Third, composite technologies will be utilized to carry the secondary data (lot and expiration) while the RSS underneath them will carry the primary data (NDC, labeler, strength, etc). Any scanner that can read RSS will still be able to read the RSS portion of the code with the primary data, even if it can't be upgraded to read the Composite portion carrying the secondary data.

COMMENTS

FOUR: The Three Year Adoption Period

Until I understood that this was impacted by the FDA's "intent to revise drug establishment and listing regulations to redefine the NCD number…." I was perplexed. I was pressing for 18 months. It was rumored that it was going to be 5. We met in the middle. I am reminded of the Law of the Speaker: A speech always expands to exceed time allotted. Give some manufacturers two years and you can count on them taking two. Give them three and they will take three. Give them five….

Half of the manufacturers are racing to get product out the door before year end. The race is on. It can be done. The feet draggers could follow suit, but probably will wait to the last minute. The argument about giving them time to use up already printed labels and containers seemed a bit out of touch with reality. Three years of stock on hand? And, if I understand correctly, the three year clock does not start ticking until 2004. There's an extra seven months anyway.

And, if it is understood that the three years is there so that they can get the new NDC's before they start barcoding, then everyone is going to be tempted to wait. Changing an NDC number takes some time and expense but it does not call for retooling the printing lines.

However, if there are compelling reasons to tie this to the redefinition of the NDC number, of which I am not aware, then I gladly concede to your better judgment.