

Butler, Jennie C

From: Gross, Mary
Sent: Friday, August 09, 2002 3:23 PM
To: Butler, Jennie C
Subject: FW: Bar code label requirements Speaker summer



FDA meeting short
summary doc

-----Original Message-----

From: Max Peoples [mailto:mpeoples@rxscan.tzo.com]
Sent: Friday, July 12, 2002 1:20 PM
To: grossm@cder.fda.gov
Subject: Bar code label requirements Speaker summer

Ms. Gross

Please see the attached speaker summary.
Would you evaluate if it is appropriate use of the committees time
to have us come and speak.
Thank you

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02N-0204

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Summary of Bar Code Label Requirements for Human Drug Products Presentation

A. General Questions

1) Which medical products should carry a bar code?...

All medication products should carry at least a National Drug Code bar code

- a) it will allow increased utilization of automation to decrease health care errors and costs
- b) non-prescription products are also administered to patients in health care facilities not just prescription products, community pharmacies and health fairs provide vaccinations

2) What information should be contained in the bar code? ...

- a) The minimum information needed is the products National Drug Code. The National Drug Code is needed to eliminate physically providing or administering the incorrect medication to a patient. The lot number and expiration date have their purposes, however, they are not involved in stopping administration or dispensing errors such as providing the wrong medication, strength or dosage form of a medication to a patient

We can provide data on the percentage of prescription errors eliminated by using National Drug Code bar code scanning prescription verification. The statistics are based on the dispensing of over 5 million community pharmacy prescriptions

3) ... should the rule adopt a specific bar code symbology....

Yes and it should have a component compatible with today's linear bar code readers.

- a) Including a compatible component will allow current bar code scanning that doesn't require any new data for its purpose to continue without having to invest in new bar code scanning equipment.

We can bring examples of bar codes that would meet this requirement

- b) Adopting ONE bar code symbology will speed up the process of adopting universal medication bar coding and will allow all the hardware manufacturers (bar code readers to bar code printers) to focus on making the best equipment at the best prices possible for a single symbology not many different symbologies. It will also allow the medication manufacturers to focus on getting bar coding done not deciding on which symbology to use.

4)... where on packages should the bar codes be placed?....

Bar codes need to be placed at least on the packaging that will reach closest to the patient, by which we mean the final package that will be opened to provide medication to the patient or the final package that will be handed to the patient.

- a) For community pharmacy the final package size that will be provided to or dispensed from needs the National Drug Code bar code. For example, monthly osteoporosis packs where the individual package is provided to the patient. The bar code needs to be on this final package, not just the larger carton that several monthly packs come in. If medication is to be taken out a bulk container and provided to the patient in a separate medication bottle this bulk container needs the National Drug Code bar code.
- b) For hospital/nursing facilities the bar code needs to be on the individual patient dose because it is that individual dose package that will get closest to the patient. Only with the National Drug Bar code bar code at this stage in the administration process (the bedside) can the bar coded data be used to verify that this is the correct medication, the correct dose, and the correct dosage form for the patient it is about to be given to.

5) ... What products already contain bar codes?...

- a) Most community pharmacy bulk manufacturer packaging has National Drug Code bar code packaging. There are a few manufacturers that bar code most of their products but not all and a fewer number that bar code none. We can provide examples.
- b) Community pharmacy and clinics are starting to use these for prescription verification
- c) The majority of unit dose/unit of use products in nursing and hospitals is not bar coded

We can bring handheld National Drug Code bar code scanning equipment currently being used in thousands of community pharmacies to eliminate misfilled prescriptions. The participants would be able to gain hands on experience with the ease of using National Drug Code bar code scanning to eliminate medication administration and dispensing errors.

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