

Butler, Jennie C

From: Gross, Mary
Sent: Friday, August 09, 2002 11:12 AM
To: Butler, Jennie C
Subject: FW: Supplemental material-barcoding



FDA Bar Code
Requirement ppt

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

From: Bruce Wray [mailto:bruce.wray@computype.com]
Sent: Monday, July 15, 2002 6:19 PM
To: 'Gross, Mary'
Subject: Supplemental material

PowerPoint with additional information helpful in formulation of the rule.
PowerPoint presentation.

I need a summary statement of your presentation which was due on July 12. We will probably not be able to accommodate powerpoint presentations in the afternoon because of the large number of people asking to speak. Can you send me a summary please? You can send me all material which will go in the public docket and we'll review everything prior to publishing the proposed rule. Thanks.

Mary
This note acknowledges the emails you've sent me about appearing at FDA's public meeting on July 26. Although, it is too early to know how speaker presentations will break down, we would be happy to hear from you. Because of the numbers of people wishing to speak, presentation times will be limited. The question about covering blood and blood products is one where we are seeking feedback. I will add your name to the list of speakers and will provide additional information about the format of the meeting, as the date gets closer. AV equipment will be available. We are also accepting written comments in the public docket that will be examined closely prior to publishing the proposed rule. Thank you for expressing interest in the barcode regulation.

Mary

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

From: Bruce Wray [mailto:bruce.wray@computype.com]
Sent: Tuesday, June 25, 2002 2:11 PM
To: 'grossm@cder.fda.gov'
Subject: Bar Code Label Requirements for Human Drug Products--Public Meeting

Here is the document that would form the basis of my presentation at the upcoming meeting. I still have not heard from you regarding whether or not you have other speakers already scheduled who will address the topics I've outlined.

<<FDA Meeting on Bar Codes for Biologic Products.doc>>

> -----Original Message-----
> From: Bruce Wray

02N-0204

APE 119

> Sent: Thursday, June 20, 2002 4:55 PM
> To: 'grossm@cber.fda.gov'
> Subject: Bar Code Label Requirements for Human Drug Products--Public
> Meeting
>

> I am considering applying to speak at the July 26 meeting. I am the
> Director of Marketing for Computype, Inc., a St. Paul, MN-based provider
> of bar code labels, printers, scanners, and software. We have served the
> blood bank, plasma, and laboratory marketplaces since the mid-1970s when
> we assistend with the drafting of the original Guidelines for the Uniform
> Labeling of Blood and Blood Components.
>

> What is the format of the presentations? Will there be a projector
> available for the use of PowerPoint?
>

> In addition to my expertise is bar code data collection in blood banks, I
> have a thorough understanding of linear and 2-D symbologies, scanning, and
> printing. My presentation would be a quick look at several topics,
> including: Why bar codes?; Current blood bank bar code standard(s); new
> bar code symbologies for increased data encodation, etc.
>

> Please let me know about the format of the presentations and whether or
> not this would overlap with a speaker you've already scheduled. Thanks.
>

> Bruce R. Wray
> Director of Marketing
> Computype, Inc.
> 2285 West County Road C
> St. Paul, MN 55113 USA
> 651/635-1234
> Fax: 651/633-5580
> bruce.wray@computype.com
>
>

Bar Code Label Requirements for Human Drug Products

Bruce Wray
Computype, Inc.

About Computype

- Bar code label, scanner, printer, software, and systems integration company
- Serving the blood bank & plasma communities since 1975
- Actively involved in original Codabar Uniform Labeling Guidelines
- Made the original suggestion to switch to Code 128 at ISBT Working Party meeting in 1989 in the Netherlands

FDA says:

- “Errors related to dispensing and administration can be minimized through the use of bar codes.”
- (If bar codes were used) “. . .the health professional would be able to verify that the **right patient** is receiving the **right drug**, in the **right dose**, and at the **right time**.”

Lessons learned through *ISBT 128* standardization efforts

- “If you build it, they will come”--NO; if the law requires it, they will come; or, if they can't compete without it, they will come
- Technology advances faster than most formal groups can make decisions
- Automating a bad system with bar codes simply enables more efficient mistakes

Lessons learned through *ISBT 128* standardization efforts

- Bar codes reduce errors (blood bank study in early 90s showed 0.00007% error rate)
- Universal compliance to a uniform standard benefits the entire industry
- **Standardized data structures are more important than a standard symbology**
- The importance of software to handle new data structures cannot be overstated

More lessons learned

- The more stakeholders are involved, the longer standardization takes. Europe is way ahead of US in *ISBT 128* implementation because of a simpler system for collection and transfusion
- Cooperation among label/printer suppliers, instrument vendors, software firms, end-users, and the FDA is a must
- Everything takes longer than expected

What options do we have today?

- Automatic identification (“Auto ID”)
 - Level 1 (linear bar code)
 - Level 1A (stacked bar code)
 - Level 2 (2-D bar code)
 - Level 3 (RFID)

Automatic identification--Level 1

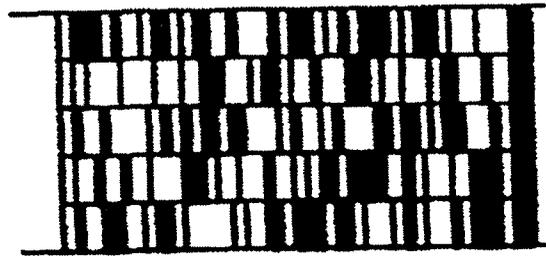
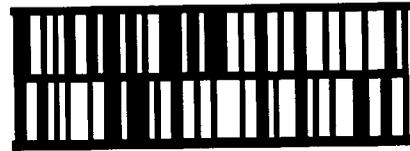
- **Linear bar code:**
 - Easy to print, easy to scan, bi-directional, self-checking and check digits available; extremely accurate; limited data encodation based on space available



Auto ID--Level 1A

■ **Stacked bar code**

A series of linear bar codes stacked directly on top of one another to form a continuous message; read by conventional laser scanners; printed similarly to linear; read-only

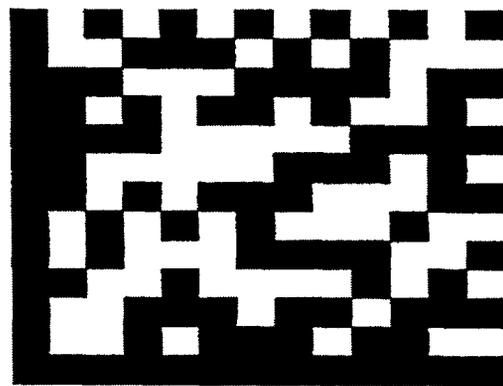


Code 49 Symbol

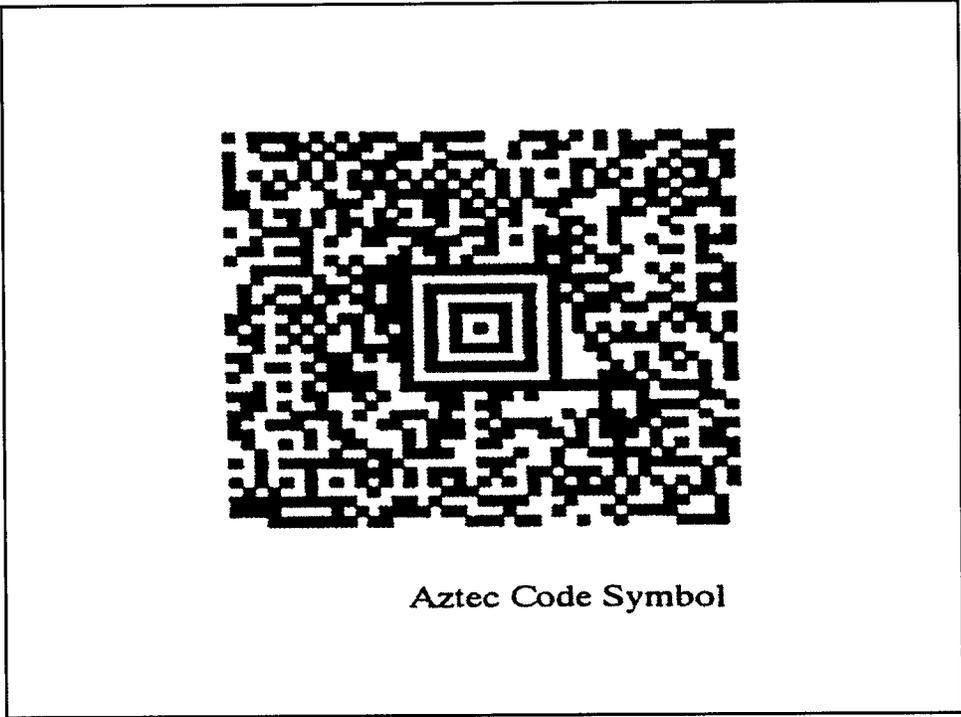
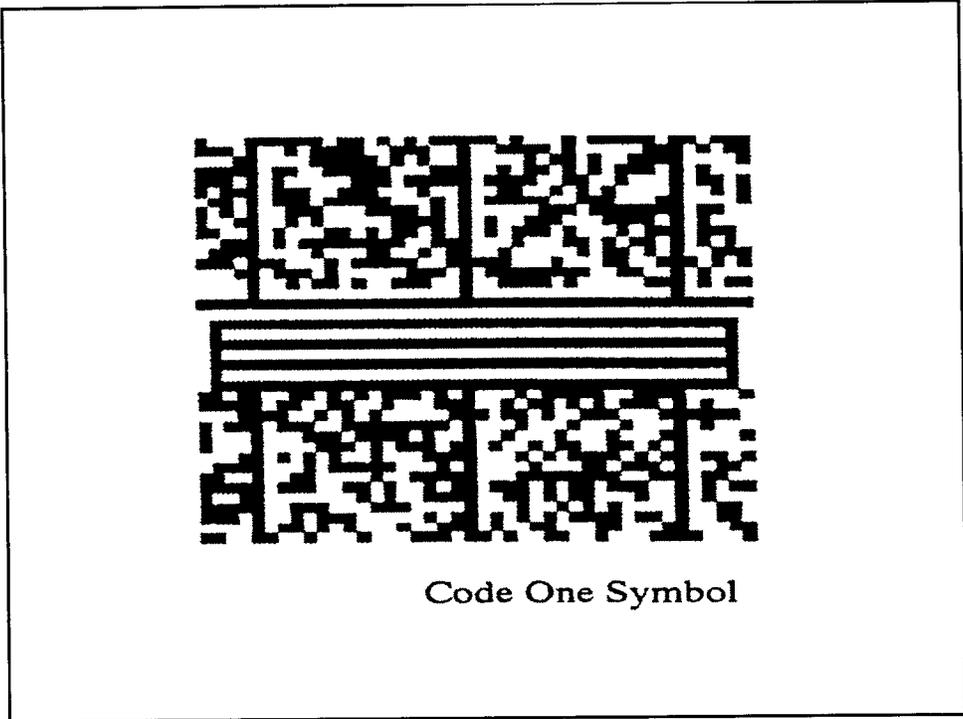
Auto ID--Level 2

- **2-D Symbol:**

Extended data capacity, error-correction capabilities, can be concatenated and truncated; requires more expensive scanners, still may need eye-readable interpretation of data



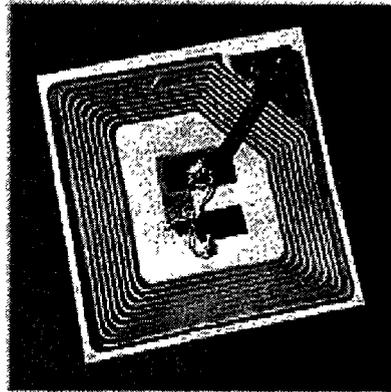
Data Matrix ECC 140 Symbol



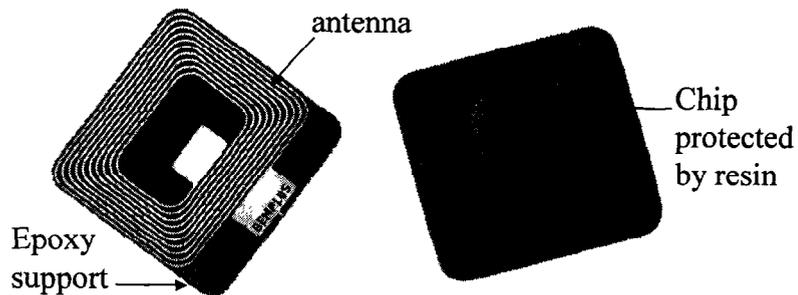
Auto ID--Level 3

■ Radio Frequency ID

Can read data from tags not visible to the system; large storage capacity; can be read/write or read-only; can be protected from environment by form factor; fairly costly technology



Passive Tag Example



The chip is activated by a reader with a pre-set frequency and sends a signal in response

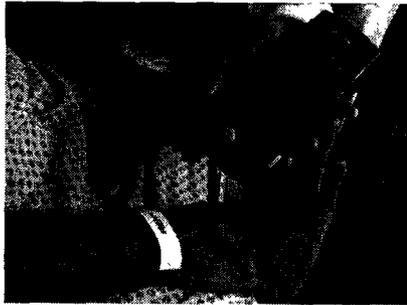
RFID Offers:

- Long-range, automatic identification that is robust, error-free, and reliable
- A unique, unalterable identification code
- Ability to store variable information
- Effective performance at extremes of temperature and humidity
- Does not require line-of-sight for operation

What will it cost?

- Contact wand: \$240
- CCD: \$420
- Linear imager: \$570
- Moving-beam laser scanner: \$890
- 2-D image reader: \$985
- PDA with scanner: \$700 - \$2500

What hardware is available?



- PDA (Personal Digital Assistant) with integrated bar code scanner
- Equipped with wireless communications capabilities
- Scan ID for real-time host access/response

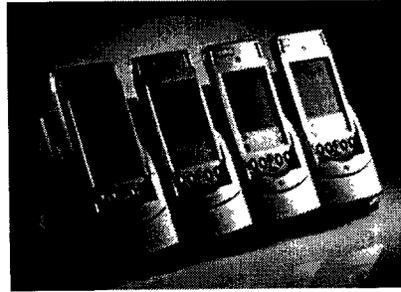
Hardware



- PDAs use either Palm- or Pocket PC-based (Windows) operating system
- Doctors typically are already Palm users
- Can display prompts-- scan blood bag, scan recipient, etc.

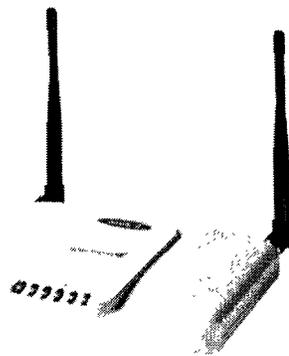
Networking options-Wired

- PDAs without wireless capability must be inserted in docking station for data downloads to host
- Eliminates cost of RF access points
- Data is not available in “real time”



Networking options-Wireless

- Wireless PDAs require “access points” for their RF signals (2.4 GHz) to be picked up and transmitted to host
- Additional hardware expense
- Application runs in “real-time”



Wireless network overview



- Scan patient on 7th floor
- Access point on 7th floor picks up signal
- Transmits data via Ethernet to host somewhere in the building
- Each device has its own IP address; no confusion

Bar code-equipped PDAs in use in healthcare:

- | | |
|-----------------------------|---------------------------|
| ■ Positive patient ID | ■ Nursing orders |
| ■ Specimen collection | ■ Charge capture |
| ■ Medication administration | ■ Supply management |
| ■ Pharmacy orders | ■ Medical record tracking |
| ■ Taking vital signs | ■ X-ray tracking |

Recommendations (1)

- **The FDA should require the use of machine-readable symbols on all human drug and biologic products**
- **Eye-readable representation of significant information should always accompany the machine-readable symbol(s)**

Recommendations (2)

- **Rather than require a specific bar code symbology (language), the FDA should mandate that an agreed-upon data structure be encoded for machine reading**

Recommendations (3)

- **Guidelines should be provided to each stakeholder industry group by the FDA which outline the minimum information content of their symbol(s), and the timeline for implementation**

Recommendations (4)

- **An Auto ID Coordinating Council should be appointed to help resolve implementation issues, made up of volunteers from the disciplines involved, bar code suppliers, and the FDA, and should be tasked with ensuring minimum data requirements are met, that the best technology available is used, and that costs are minimized**