

Butler, Jennie C

From: Gross, Mary
Sent: Friday, August 09, 2002 11:42 AM
To: Butler, Jennie C
Subject: FW: Summary Statement-barcode



FDA Meeting
Summary Statement

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

From: Bruce Wray [mailto:bruce.wray@computype.com]
Sent: Monday, July 15, 2002 4:41 PM
To: 'Gross, Mary'
Subject: Summary Statement

Attached is a brief summary statement in MSWord format. I will be sending the rest of the material shortly.

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

From: Gross, Mary [mailto:GrossM@cder.fda.gov]
Sent: Monday, July 15, 2002 3:12 PM
To: 'Bruce Wray'
Subject: RE: Bar Code Label Requirements for Human Drug Products--Public Meeting

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

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

From: Bruce Wray [mailto:bruce.wray@computype.com]
Sent: Monday, July 15, 2002 11:00 AM
To: 'Gross, Mary'
Subject: RE: Bar Code Label Requirements for Human Drug Products--Public Meeting

I have completed the PowerPoint presentation I would like to use at the upcoming meeting. I also have a paper that contains additional information on bar code symbologies, etc. that might be helpful. At what point do these need to be submitted to you for use at the meeting?

I can make copies of the paper and provide them on the 26th; in addition, I can provide copies of the hand-outs from the presentation itself. Please let me know at your earliest convenience what would be the most helpful. Thanks for your help.

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

From: Gross, Mary [mailto:GrossM@cder.fda.gov]
Sent: Wednesday, June 26, 2002 8:08 AM
To: 'Bruce Wray'
Cc: Lewis, Richard; Phillips, Jerry; McGinnis, Tom

02N-0204

APE 118

Subject: RE: Bar Code Label Requirements for Human Drug Products--Public Meeting

Hi:

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@cdcr.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
> 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 assist 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
>
>

Summary Statement for Public Meeting on Proposed Rule by FDA Requiring Bar Code Identification on Human Drug and Biologic Products

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).
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.
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.
4. An Auto ID Coordinating Council should be appointed to help resolve implementation issues. The AIDCC would be made up of volunteers from the disciplines involved in the new requirements, bar code suppliers, and the FDA. It would be charged with ensuring minimum information requirements are met, that the best technology available is used, and that costs to individual institutions and firms is minimized.

Submitted by

Computype, Inc.

2285 West County Road C

St. Paul, MN 55113

800/328-0852

www.computype.com

Computype representative:

Bruce R. Wray

Director of Marketing

651/635-1234

bruce.wray@computype.com