

Butler, Jennie C

From: Gross, Mary
Sent: Friday, August 09, 2002 11:10 AM
To: Butler, Jennie C
Subject: FW: HDMA speaker request for July 26 bar code labeling meeting

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

From: Clowers, Lisa [mailto:lclowers@hdmanet.org]
Sent: Tuesday, July 16, 2002 8:34 AM
To: Gross, Mary
Subject: RE: HDMA speaker request for July 26 bar code labeling meeting

Mary,

Diane Goyette sent the summary last week but I've attached again for your convenience.

Take care and let me know if you need anything else.

Lisa

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

From: Gross, Mary [mailto:GrossM@cder.fda.gov]
Sent: Monday, July 15, 2002 5:01 PM
To: Clowers, Lisa
Subject: RE: HDMA speaker request for July 26 bar code labeling meeting

Lisa:

I will need a summary of his remarks as soon as possible. Thanks.

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

From: Clowers, Lisa [mailto:lclowers@hdmanet.org]
Sent: Monday, July 15, 2002 10:26 AM
To: Gross, Mary; Goyette, Diane
Cc: Bickel, Lori; Gallo, Michael
Subject: RE: HDMA speaker request for July 26 bar code labeling meeting

Mary,

Thanks for your response. We will need to find a hotel nearby for Bob to stay over. He is from California. Do you have any that you could recommend?

Lisa

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

From: Gross, Mary [mailto:GrossM@cder.fda.gov]
Sent: Monday, July 15, 2002 10:16 AM

8/12/2002

02N-0204

APE 116

To: Goyette, Diane
Cc: Clowers, Lisa; Bickel, Lori
Subject: RE: HDMA speaker request for July 26 bar code labeling meeting

I will add Robert Schwartz to the list of speakers in the afternoon and will get back to you with more details about the meeting. Thank you for your interest.

Mary

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

From: Goyette, Diane [mailto:dgoyette@hdmanet.org]
Sent: Saturday, July 13, 2002 7:34 PM
To: Gross, Mary; Gross, Mary
Cc: Clowers, Lisa; Bickel, Lori
Subject: RE: HDMA speaker request for July 26 bar code labeling meeting

Mary - I did not get this response from you until Saturday, but of course we would like some time to speak, as indicated in my Thursday e-mail. Robert Schwartz would be the speaker. I will ask Lisa Clowers to give you a call on Monday since I will be on vacation. Thank you! Diane

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

From: Gross, Mary [mailto:GrossM@cder.fda.gov]
Sent: Fri 7/12/2002 4:33 PM
To: Goyette, Diane; Gross, Mary
Cc: Clowers, Lisa; Bickel, Lori
Subject: RE: HDMA speaker request for July 26 bar code labeling meeting

We will be happy to hear from your organization. The panel selections have been made but if you are interested in speaking in the afternoon, I will include you with other speakers. Time will be very short because of the significant interest in this issue. If you would like some time, please let me know this afternoon. Thanks.

Mary

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

From: Goyette, Diane [mailto:dgoyette@hdmanet.org]
Sent: Friday, July 12, 2002 12:21 AM
To: grossm@cder.fda.gov
Cc: Clowers, Lisa; Bickel, Lori
Subject: HDMA speaker request for July 26 bar code labeling meeting

Ms. Gross - I've been having some problems with my computer, so will plan to also fax these materials to you on Friday in case there were e-problems. If you have any questions or need for additional information, please contact Lisa Clowers at HDMA [lclowers@hdmanet.org 703-787-0000 ext 222] as I will be out of town on vacation next week.

HDMA hopes to play an active role in the July 26 meeting and bar code labeling activities going forward and we appreciate any help you can give us in securing a spot at the speaker table.

Diane Goyette
HDMA Director, Regulatory Affairs
1275 K Street, NW #1212
Washington, D.C. 20005
(703) 787-0000 ext 240
(202) 312-5005 (fax)

Summary of HDMA Presentation for July 26 Public Meeting Regarding Bar Code Labeling Requirements

The HDMA speaker would be Robert Schwartz, current HDMA Chairman of the Board and President of the Barnes Division of H.D. Smith Wholesale Drug Company.

Mr. Schwartz will present an overview of HDMA and its membership, discuss the current state of the industry's acceptance of bar codes, and describe the technology available to support this initiative. Mr. Schwartz will also highlight the benefits of bar coding, provide industry statistics related to bar code usage in the manufacturer, distributor and customer settings and explain the impact changes to identification systems would have on the healthcare supply chain.

HDMA's Support of Efforts to Reduce Medical Errors and History with Bar Codes:

HDMA has been an active participant in the National Coordinating Council for Medication Error Rates and Prevention since 2000. We have been pioneers in promoting the usage of bar code standards in the healthcare industry since the early 90's. We have worked collaboratively with the Health Industry Business Communications Council (HIBCC) and the Uniform Code Council (UCC) to develop voluntary guidelines for the industry, and have developed an industry position on the usage of bar codes

Current State of the Industry and Technology Capabilities

Mr. Schwartz will review a flow map showing the entire pharmaceutical distribution chain, noting the places where a bar code labeling requirement would have the most impact. He will discuss current levels of bar code usage, providing statistics related to manufacturer, distributor and pharmacy settings.

Benefits of Bar Coding

Mr. Schwartz will discuss the benefits of bar coding in ensuring the accuracy of medication identification and administration and improving efficiencies within the medication-use process, monitoring of drug-use trends, and overall efficiencies in the supply system and public health and patient safety.

HDMA's Position on Bar Codes

- Identify all levels of packaging, (SKUs, inner packs and shipping cases) with a barcode symbol or symbols that comply with the HDMA Numerical and Automatic Identification of Drug Products Guideline, as revised.
- Use the National Drug Code (NDC) as defined by the Food and Drug Administration (FDA) as the preferred numbering system for drug products.

- Follow bar code standards published by the Uniform Code Council (UCC) for OTC drug products and Health Industry Business Communications Council (HIBCC) for medical-surgical devices for all packaging levels.
- Apply bar code labeling as early in the supply system as possible, e.g. manufacturing or packaging.
- Conduct appropriate symbology evaluations to determine optimal technology in applying and scanning bar codes.
- Implement bar coding of unit of use and small packages (goal: to have all drug and device products used at the patient bedside carrying a barcode).
- Use bar codes internally wherever possible. Use of bar codes to identify healthcare products has been shown to reduce labor costs in distribution and dispensing while, at the same time, reducing errors.

Impact of Bar Code Changes

Mr. Schwartz will discuss the potential impacts of a bar code requirement on the health care distribution chain. He will discuss the large costs that would be incurred if lot number and expiration date were required as part of the bar code label, as is being discussed. He will discuss the HDMA view that FDA be flexible as to symbology chosen. He will describe the overall huge economic impact on manufacturers and distributors in the areas of packaging technology, equipment components, integration of computer systems, and other implementation costs.