CDER Live! will explore the background for revising the content and format of prescription drug labeling and the anticipated improvements in risk communication and management resulting from these new requirements.

The panel will offer some guidance for developing and converting labeling, and they will draw on questions presented previously during public meetings to further clarify this important FDA initiative.

The panel will also discuss companion initiatives and steps FDA is taking to assist industry in implementing the new labeling requirements.

LEARNING OBJECTIVES

- Describe the major content and format changes to prescription drug labeling and the rationale for these changes
- Describe general principles for developing and converting labeling as described in the draft “Implementation” guidance
- Discuss the new prescription drug labeling requirements as a risk communication and management tool

TARGET AUDIENCE

This program is designed for personnel from:

- Medical product sponsors
- Project management
- Medical writing
- Medical communications
- Information management
- Marketing/sales
- Clinical safety/pharmacovigilance
- Manufacturing/drug substance, drug product, packaging
- Regulatory affairs
- Document management
- Information technology
- Information management
- Clinical data management
- Quality assurance/quality control
- Dictionaries/data standards
- eClinical
- Project management
- Physicians
- Pharmacists

MODERATOR

NANCY D. SMITH, PhD
Director, Office of Training and Communications, CDER, FDA

GUESTS

RACHEL E. BEHRMAN, MD, MPH
Deputy Director, Office of Medical Policy, CDER, FDA

STEVEN K. GALSON, MD
Director, CDER, FDA

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Accreditation and Credit Designation

The Drug Information Association is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Drug Information Association designates this educational activity for a maximum of 3 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. This program is designated for 3 contact hours or 0.3 continuing education units (CEUs). 286-000-06-031-L04.

The Drug Information Association (DIA) has been reviewed and approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1620 I Street, NW, Suite 615, Washington, DC 20006. The DIA has awarded up to .3 continuing education units (CEUs) to participants who successfully complete this program.

If you would like to receive a statement of credit, you must attend the program and return the credit request and evaluation forms to the DIA. Statements of credit will be issued within 30 days of receipt of these forms.

Disclosure Policy: It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.
Three Ways You Can Participate in the Video Conference

1. View the Videoconference at Your Site: Complete the registration form on page 3 and send it along with payment to DIA. (Please note registration deadline date.) To participate you will need either: a) a steerable C-band satellite dish or b) a digital videoconference room. For those who will participate in the program using a land-based videoconference room, we have arranged with Wire One to coordinate with you.

IMPORTANT (after registering on the DIA website): If you plan on receiving the content via videoconference, YOU MUST contact Wire One Communications by email (reservations@wireone.com) or phone (1-800-987-7260) to provide information on your video conference system and billing information. Before calling Wire One Communications you must call Cheryl Buckage at 215-442-6194 to acquire the reservation number (for the May 9, 2006 Drug Information Association conference). Wire One Communications will bill you directly for their services.

2. Participate in the Video Conference live on-site at CDRH Studio, 16071 Industrial Drive, Gaithersburg, MD 20850

3. View the Videoconference by Webcast: You may view the program from your home or office. See page 3 for registration details.

To receive the webcast, your computer must have:

1) Pentium 166 processor or equivalent,
2) 32 MB RAM,
3) 56k or faster modem,
4) 16-bit sound card and speakers,
5) 65,000-color video display card,
6) Windows 95 Operating System (or better), or UNIX or MAC,
8) MS Internet Explorer 3.0 or higher OR Netscape Navigator 3.0 or higher,
9) Your company’s corporate network must accept real audio traffic through its firewall – if it doesn’t, you may be able to receive it from your home, if your home PC has the equipment listed.

NOTES: 1. Please see page 3 for instructions about two mandatory technical checks to perform before registration.
2. We do NOT recommend viewing the program through AOL. The high volume of traffic on their network could cause audio dropout and/or reception problems.

Benefits You Will Receive

As a Videoconference attendee:

1) Viewing access to the live satellite videoconference;
2) One Site Facilitator Manual including technical information for viewing the program;
3) Opportunity to network with colleagues;
4) Access to telephone and fax machines for live interactive dialogue with FDA panel members;
5) Will receive a complimentary copy of a videotape of the conference.

As an Internet viewer:

1) Live high-quality audio and 15 fps video during the broadcast (depending on Internet activity and connectivity);
2) The ability to phone or fax questions directly to the panelists during the broadcast;
3) The convenience of receiving the broadcast on your own computer;
4) The ability to view the archived version of the webcast for 60 days after the satellite conference.

LICENSE INFORMATION

The downlink fee must be prepaid before DIA can send the Site Facilitator Manual which includes the satellite coordinates. DIA will not be liable for failure to deliver the conference or packets of materials due to circumstances beyond its control. DIA warrants that it will deliver a broadcast quality signal to the satellite. However, DIA is not responsible for local reception, nor is it responsible for any costs associated with the local site such as meeting space, viewing equipment, satellite dish rental, etc.

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CANCELLATIONS: No refunds will be provided in the event of a participant’s cancellation since all costs for this satellite conference have been prepaid by DIA. DIA reserves the right to modify or cancel programs and/or substitute presenters or panelists without liability. DIA is not responsible for failure to deliver programs due to circumstances beyond our control. DIA is not liable for technical failure of equipment at downlink sites.
HOW TO REGISTER

On or Before MAY 7, 2006

1. Register online at http://www.diahome.org
2. Fax the completed registration form with a valid credit card number to DIA at +1-215-442-6199
3. Send the completed registration form with a check enclosed to Drug Information Association, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA.

After MAY 7, 2006

You must contact DIA by telephone at +1-215-442-6100 to verify availability. Time will be needed to make the technical arrangements and to forward the necessary confirmation materials to you.

Questions?

DIA’s website is http://www.diahome.org

If you have any questions concerning this video conference, call Cheryl Buckage at +1-215-442-6194 or contact us by email at Cheryl.Buckage@diahome.org

REGISTRATION FORM – MAY 9, 2006 CDER LIVE! I.D. #06225

Yes, I would like to participate in the May 9 Satellite Video Conference

☐ Please register my organization’s site for participation via downlink Purchase of downlink includes a complimentary copy of a videotape of the conference. Videotape is not available for individual purchase.
☐ Please register me for participation via Webcast

Please check the appropriate fee(s)

☐ Organization Downlink Fee (1 Site) $1,800
  ☐ Via Satellite ☐ Via Video Conference Room
☐ Individual via Webcast $ 350
☐ Group Site via Webcast $ 899
☐ Live participation at CDRH Studio, Gaithersburg, MD (Attendance limited to 75 – Registrants must be on site by 12:30 pm EDT) $ 250

TOTAL DUE ____________

For questions concerning the program or registration, please contact Cheryl Buckage at DIA by Telephone: +1-215-442-6194 Fax: +1-215-442-6199 email: Cheryl.Buckage@diahome.org

Technical Checks

1. To insure your equipment meets all the above requirements click on the link below. http://www.visualwebcaster.com/syscheck/systemcheck.html

If you do not perform these checks prior to the presentation, we cannot guarantee you will be able to view the webcast.

NOTE: All Conference Materials, including Confirmation and Facilitator’s Manual, will be forwarded to the person indicated below.

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