



! CDER LIVE !

PDUFA III: *Building on Success*

NOVEMBER 5, 2002

1:00 PM to 3:30 PM EST

MODERATOR

Deborah Henderson

Director, Office of Executive Programs,
CDER, Food and Drug Administration

GUESTS

Steven Galson, MD, MPH

Deputy Director, CDER, Food and Drug
Administration

John Jenkins, MD

Director of the Office of New Drugs,
CDER, Food and Drug Administration

Victor Raczkowski, MD

Director, Office of Drug Safety, CDER
U.S. Food and Drug Administration

Timothy Franson, MD

Vice President of Clinical Research
and Regulatory Affairs-US
Lilly Research Laboratories

Alan Goldhammer, PhD

Associate Vice President for Regulatory Affairs
Pharmaceutical Research and Manufacturers of
America (PhRMA)



ACPE: This program is offered in cooperation
with ABcomm, Inc. ABcomm, Inc. is approved by
the American Council on Pharmaceutical Education
as a provider of continuing pharmaceutical
education. ACPE Program I.D. No. 811-999-02-681-L04.

Participants who attend this program and complete the program
evaluation form may earn up to 2.50 contact hours (.250 CEUs) of
continuing education credit. This credit is acceptable by all
boards of pharmacy that recognize ACPE-approved providers.

This course has been designated by the California Board of Pharm-
acy as meeting its C.E. requirements for 2.50 hours of credit.
Pharmacists attending this program may earn up to 2.50 hours
of C.E. credit.

Learning Objective: To address issues related to approval
of new drugs and the many facets of risk management faced
by industry, CDER-FDA, and the healthcare community.

OVERVIEW

The focus of this program will be a discussion of the PDUFA III agreement and how the new agreement builds on the success that FDA has achieved under PDUFA over the past decade. A major area of discussion will be on how the new agreement is expected to provide additional resources to better balance the workload with the resources. A second major focus will be on the new risk management components of PDUFA III and how they are expected to have a positive impact on the safety of new drugs.

TARGET AUDIENCE

- Industry personnel involved with new drug approval and drug safety issues
- Members of academia and the healthcare community

Information on how you can participate – page 2.
Registration Form – page 3.

VISIT OUR WEBSITE: www.diahome.org

Three Ways You Can Participate in the Video Conference

- **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- or Ku-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 V-Span to coordinate with you.

IMPORTANT: After you register, YOU MUST contact **V-SPAN** at reservations@vspan.com or call **V-SPAN's Reservations Team** by phone 1-800-987-7260. Please indicate to **V-SPAN** this conference is for the November 5, 2002 DIA Video Conference. If you have questions concerning your technical capabilities, please contact Marc Wezner at +1 610-382-4061 or by email: marc.wezner@vspan.com. **V-Span** will bill you directly for their services.

- **View the Videoconference at an Open Site:** If you are interested in viewing the conference at an Open Site, please check DIA's website, <http://www.diahome.org> which will list any participating Open Sites. If your organization is interested in being listed on DIA's website as an Open Site, please contact Cheryl Buckage at the DIA address on page 3.
- **View the Videoconference by Webcast:** You may view the videoconference from your home or office. See page 3 for registration details. To receive the videoconference over the Internet, your computer must have:
 - 1) Pentium 166 processor or equivalent,
 - 2) 32 MB RAM,
 - 3) 28.8k 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,
 - 7) RealPlayer 8.0 (free to download from www.real.com),
 - 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.

NOTE: 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.

■ 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.

Licensees should be aware that due to the sometimes sensitive nature of the content of FDA broadcasts, there may be a time that a program could get cancelled or replaced by another title within a similar subject area. DIA/FDA will make every effort to provide sufficient notification of a change of title or cancellation. DIA will provide a credit or refund only in those cases where a cancellation has occurred, not when a substitute program is provided.

This licensing agreement gives the Licensee the right to view and participate in the live broadcast. The program shall not be rebroadcast, transmitted by cable, or transmitted on any open or closed circuit system unless a multiple license fee has been paid. The Licensee shall also honor the following provisions:

Videoconference Sites: Any Licensee choosing to audio or videotape shall have the right to retain the recorded copy of the program for playback/ audiovisual use solely by Licensee for educational purposes only. This program may not be edited or altered by the Licensee. The Licensee agrees not to duplicate, sell or rent the recorded copy of the program without the express written permission of DIA.

Webcast Sites: **1.** DIA accepts no liability for problems that may be encountered as a result of high traffic on the WWW; **2.** The Licensee has the right to view the program live or access the archived version at any time during a 60-day period beginning November 6, 2002; and **3.** DIA will provide the Licensee with specific information for accessing the webcast. This information must be treated as proprietary and not given to anyone else.

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.**

OPEN SITES

If you are interested in participating as an open site,
please contact Cheryl Buckage by email at

Cheryl.Buckage@diahome.org

Questions? DIA's website is <http://www.diahome.org>.
If you have any questions concerning this videoconference,
call Cheryl Buckage at +1 215 442 6194 or contact us
by email at Cheryl.Buckage@diahome.org.

How to Register:

■ On or Before OCTOBER 29, 2002:

Fax the completed registration form with a valid credit card
number to DIA at +1 215 442 6199 **OR**

Send the completed registration form with a check enclosed
to Drug Information Association, 800 Enterprise Road, Suite
200, Horsham, PA 19044-3595.

■ After OCTOBER 29, 2002:

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.

REGISTRATION FORM – NOVEMBER 5, 2002 !CDER LIVE! I.D. #02055

Yes, I would like to participate in the November 5 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) \$1,600
 Via Satellite Via Videoconference Room
- If participating by downlink and by your own satellite, does your
satellite Have Ku-band or C-band capabilities? (please circle one or both)
- Participation via Webcast \$100

Total _____

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

For all technical questions,
please contact Sam Lynott by
Telephone: +1 703 642 6505
Fax: +1 703 642 6005
email: lynott@lmpdg.com

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

Payment Method: Check Enclosed VISA MC AMEX

Credit Card # _____ Expiration Date _____

Cardholder's Name (Please Print) _____ Cardholder's Signature _____

Name _____ Title _____

Organization _____ Division _____

Street Address (No P.O. Boxes Please) _____

City _____ State _____ Zip/Postal Code _____ Country _____

Telephone _____ Fax _____

email _____