FDA HANDS-ON WORKSHOP
Implementing the Final Rule on the Content and Format of Prescription Drug Labeling

May 4-5, 2006 | Bethesda North Marriott Hotel & Conference Center, MD

CONFERENCE HIGHLIGHTS
• Get ready for the new US prescription drug labeling regulations that will go into effect on June 30, 2006
• FDA speakers explain the prescription drug labeling rule and new guidances
• Hands-on exercises converting labeling to the new format, led by FDA instructors
• Substantial interaction between FDA and industry participants in breakout sessions

LEARNING OBJECTIVES
At the conclusion of this meeting, participants should be able to:
► Describe the major content and format changes to prescription drug labeling and the rationale for the changes.
► Describe the criteria for including information in Highlights.
► Explain the principles for allocating information to various sections of the Full Prescribing Information when updating labeling from the current to the new format.

OVERVIEW
Unique Hands-on FDA Workshop
In a plenary session in the morning of day one, FDA speakers will present the new format and content requirements for prescription drug labeling that published on January 24, 2006, as well as an overview of general principles for converting labeling to the new format as described in the new draft implementing guidance. The FDA speakers will also discuss the essential concepts for developing specific labeling sections from the new final and draft guidances on content and format of the Adverse Reactions, Clinical Studies, Warnings and Precautions, Contraindications and Boxed Warnings sections of US prescribing information.

TARGET AUDIENCE
This meeting will benefit those who are engaged in US product labeling from a clinical safety/pharmacovigilance, technical, regulatory compliance, medical, and legal perspective and who will participate in creating labeling in accordance with the new format and content requirements for prescription drug labeling that published in the Federal Register on January 24, 2006.

It will also benefit those who have to understand and implement FDA’s new guidances on the content and format of the Adverse Reactions and Clinical Studies sections, and interpret the draft guidance on the content and format of the Warnings and Precautions, Contraindications and Boxed Warnings sections of US prescribing information.

FOR MEETING INFORMATION, CONTACT:
Jolene McNeil | Phone +1-215-293-5810 | email Jolene.McNeil@diahome.org
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 11.5 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

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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 1.2 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.

Learning Objectives: At the conclusion of this meeting, participants should be able to:

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Statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

TRAVEL AND HOTEL

The most convenient airport is Reagan National Airport and attendees should make airline reservations as early as possible to ensure availability. The Bethesda North Marriott Hotel & Conference Center is holding a block of rooms at the reduced rate below until April 12, 2006, for the DIA meeting attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $209  Double $209

Please contact the Bethesda North Marriott Hotel & Conference Center by telephone at +1-800-228-9290 or +1-301-822-9200 and mention the DIA meeting. The hotel is located at 5701 Marinelli Road, North, Bethesda, MD 20852, USA.

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To obtain schedule information and the best fares, call United Airlines’s Specialized Meeting Reservations Center at 1-800-521-4041. Make sure you refer to Meeting ID Number 571AK. Dedicated reservationists are on duty 7 days a week from 8:00 AM to 10:00 PM EST.

This special offer applies to travel on domestic segments of all United Airlines, United Express, PED, and United code share flights (UA*, operated by US Airways, US Airways Express and Air Canada).

Participants with Disabilities:

DIA meeting facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the meeting if requested at least 15 days prior to meeting. Contact the DIA office to indicate your needs.

DRUG INFORMATION ASSOCIATION  http://www.diahome.org

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Overview of the New Labeling Requirements
Rachel E. Behrman, MD, MPH, Deputy Director, Office of Medical Policy, CDER, FDA

An overview of the new requirements will be presented, including Highlights, Contents and Full Prescribing Information, with an emphasis on new or revised requirements. The implementation schedule for affected products will also be reviewed.

Labeling Section Guidances
Robert J. Temple, MD, Director, Office of Medical Policy and Office of Drug Evaluation I, CDER, FDA

The three new section-specific guidances (Clinical Studies (final), Adverse Reactions (final), and Warnings and Precautions, Contraindications, and Boxed Warnings (draft)) provide recommendations for developing these labeling sections. This presentation will describe the essential concepts from these guidances, including how to select, present, and organize information in these sections.

Implementation Guidance
Janet Norden, MSN, RN, Associate Director for Regulatory Affairs, Office of Medical Policy, CDER, FDA

The new Implementing the New Content and Format Requirements (draft) guidance is intended to help industry with complying with the new labeling requirements. This presentation will review general principles for converting labeling from the “old” to the “new” format, identify issues to consider when developing Highlights, and present procedural and formatting information.

General Questions & Answers Panel

This session provides an opportunity for meeting participants to get answers to questions about the new rule and guidances, as well as about process issues such as submitting labeling supplements and interacting with FDA review divisions.

Panelists
Rachel E. Behrman, MD, MPH, Deputy Director, Office of Medical Policy, CDER, FDA
John K. Jenkins, MD, Director, Office of New Drugs, CDER, FDA

Prototype Development Breakout Sessions Continued

Meeting participants will break out into small groups to convert labeling for a fictitious drug from the old to the new format. The breakout groups will be led by FDA staff. Participants will receive hands-on experience developing labeling and receive feedback during this dynamic session.

Prototype Development Breakout Sessions’ Group Reports

A volunteer from each breakout group will briefly share their group’s experience with developing prototype labeling, including challenges encountered, solutions identified, and outstanding questions. FDA staff will be available to offer feedback, respond to questions, and provide examples of additional labeling challenges.

Prototype Development Questions & Answers

FDA staff will be available to answer questions that arise during the breakout sessions.

General Questions & Answers Panel

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Prototype Development Breakout Sessions’ Group Reports Continued

3:30 PM WORKSHOP ADJOURNED
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Bethesda North Marriott & Hotel Conference Center, MD, USA
MAY 4-5, 2006  Meeting ID #06024

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CONTACT INFORMATION
Contact Jolene McNeil at the DIA office by:
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email Jolene.McNeil@diahome.org

Registration Fees
Registration fee includes refreshment breaks, luncheons, and reception (if applicable),
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Administrative fee that will be withheld from refund amount:
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Tutorial = $50

Cancellations must be in writing and be received by the cancellation date above.
Registrants who do not cancel by that date and do not attend will be responsible for
the full registration fee paid. Registrants are responsible for cancelling their own hotel
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but membership is not transferable. Please notify DIA of any such substitutions as soon
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