Improving Patient Safety by Enhancing the Container Labeling for Parenteral Infusion Drug Products

January 11, 2007 at Lister Hill Auditorium, NIH Campus

9000 Rockville Pike, Building 38A Bethesda, MD 20815

7:30am	Sign-in
8:00am	Welcome - purpose and scope of meeting, types of products to be discussed, general remarks on program *Gerald Dal Pan, M.D., M.H.S, Director, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA)*
8:10-8:30am	Scope of medication errors *Mike Cohen, R.Ph., M.S., Sc.D., President, Institute for Safe Medication Practices (ISMP)*
8:30-8:45am	Historical perspective *Diane D. Cousins, R. Ph., Vice President, Department of Healthcare Quality and Information, Standards Division, U.S. Pharmacopeia (USP)*

Session I - Container Label Information Requirements

8:45-8:50am	Moderator introduction to Session I *Allen Vaida, Pharm.D., Executive Vice President, Institute for Safe Medication Practices (ISMP)*
8:50-9:10am	Overview of USP requirements *James W. Kelly, M.S., Ph.D., R.Ph., Scientist, Department of Healthcare Quality and Information, Standards Division, U.S. Pharmacopeia (USP)*
9:10-9:35am	Overview of FDA requirements *Eric Duffy, Ph.D., Director, Division of Post-Marketing Drug Evaluation/Office of New Drug Quality Assessment, Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA)*
9:35-10:00am	Small Volume Parenterals (SVP) - manufacturer presentation on the challenges from the industry perspective *Vicki Drews, RAC, Associate Director, Global Regulatory Affair, Baxter International, Inc.*
10:00-10:15am	**BREAK**
10:15-10:40am	Large Volume Parenterals (LVP) - manufacturer presentation on the challenges from the industry perspective *Mary Baker, Pharm.D., Senior Medical Manager, Global Medical Affairs and Tom Willer, Ph.D., Global Regulatory Affairs Director, Hospira, Inc.*

10:40-11:20am Panel discussion and questions from the audience

Panel: Mike Cohen/ISMP, Diane Cousins/USP, James Kelly/USP, Erik Duffy/FDA, Vicki Drews/Baxter, Mary Baker/Hospira, Tom Willer/Hospira

11:20 -11:30am Moderator wrap-up of Session I; instructions for lunch

11:25am-12:45pm **LUNCH**

Session II - Minimizing Confusion Among Product Labels

12:45-12:50pm Moderator introduction to Session II

Shawn C. Becker, M.S., B.S.N., R.N., Director, Patient Safety Initiatives, Department of Healthcare Quality and Information, Standards Division, U.S. Pharmacopeia (USP)

12:50-1:15pm Nursing perspective

Debora Simmons, R.N., M.S.N, Senior Clinical Quality Improvement Analyst, Institute for Healthcare Excellence, University of Texas M D Anderson Cancer Center

1:15-1:40pm Pharmacy perspective

Timothy Lesar, Pharm.D., Director of Pharmacy, Albany Medical Center

1:40-2:05pm Manufacturer presentation on industry solutions and proposals

Susan Olinger, Corporate Vice President, Regulatory Affairs B. Braun Medical, Inc.

2:05-2:55pm Panel discussion and questions from the audience

Panel: Mike Cohen/ISMP, Diane Cousins/USP, James Kelly/USP, Erik Duffy/FDA, Vicki Drews/Baxter, Mary Baker/Hospira, Tom Willer/Hospira, Debora Simmons/University of Texas, Tim Lesar/Albany Medical Center, Susan Olinger/B. Braun

2:55-3:00pm Moderator wrap-up of session II; instructions for the open public hearing

3:00-3:15pm **BREAK**

Open Public Hearing

3:15 -4:15pm Speakers who submitted written or electronic requests to speak should make their presentations during the time slot assigned to them

Meeting Summary and Closing Remarks

4:15-4:25pm Meeting summary

Carol Holquist, R.Ph., Director, Division of Medication Error and Technical Support, Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA)

4:25-4:30pm Final comments

Gerald Dal Pan, FDA

During this meeting we will explore the following questions:

1. What are the best solutions to differentiate look-alike container labels of pre-mixed LVPs and SVPs containing different medications (among different product lines from the same manufacturer and across different manufacturer product lines)?

2. Would the use of color differentiation on labels prevent medication errors? Can different colors be used on intravenous bags? If not, what are the barriers and possible ways to address them?

3. What information currently required on intravenous container labels can be eliminated or placed elsewhere in order to make room for more important information such as barcodes, larger font size for drug names, new standard ways to express drug concentration, and product warnings? How can industry make the best use of the limited space on labels? What type of standards for layout and type size would need to be applied to correct the confusion among the products?

4. How does the lack of standardization in the expression of medication concentrations on labels contribute to error? How can we standardize the expression of drug concentrations on IV drug container labels?

5. How do the similar labels for Sterile Water for Injection, Sterile Water for Irrigation, and Sterile Water for Inhalation lead to medication errors? How can the label for sterile water be improved to minimize the risk of confusing the different routes of administration?

6. What strategies are there to prevent inadvertent administration of solutions not intended for parenteral IV use?

7. What are the regulatory, technological, and resource (cost) barriers that would need to be eliminated to address the challenges identified today? What are some practical solutions to address these challenges?

Other Information

Submitting comments:
You may submit written or electronic comments to the Division of Dockets Management. Send written comments to Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments to the docket will be accepted until April 12, 2007. Comments are to be identified with the docket number **2006N-0465**.

Transcripts:
Copies of the transcript may be requested in writing from the Freedom of Information Office, Food and Drug Administration, 5600 Fishers Lane, Room 6-30, Rockville, MD 20857, approximately 20 working days after the meeting and at a cost of 10 cents per page or on compact disc at a cost of $14.25 for each compact disc. Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at http://www.fda.gov/cder/meeting/parenteral_labeling.htm.

Please see the Federal Register notice http://www.fda.gov/OHRMS/DOCKETS/98fr/E6-20035.htm for further details on this public meeting.