Activity Outline
DDI Webinar Series: Ongoing Role of FDA in Medication Error Prevention
June 6, 2017 1:00-2:00pm EDT
Webinar

Description
This series of educational webinars is designed to aid physicians, physician assistants, nurses, pharmacists, pharmacy technicians, students, and other healthcare professionals, to provide better patient care by knowing how to find relevant FDA regulatory information that will improve drug safety. This webinar will provide information on the Division of Medication Error Prevention and Analysis (DMEPA)'s role in preventing and addressing medication errors. Regulatory action taken to address recent medication error reports will be explored, as well as the role of pharmacists in identifying, preventing and mitigating medication errors.

Series Objectives
1. Explain how to utilize FDA's drug information, medication safety resources, and regulatory guidance documents, to improve delivery of patient care and optimize outcomes.
2. Describe and inform health care providers of recent labeling changes which would impact prescribing and medication management to optimize patient care.

Session Learning Objectives After completion of this activity, the participant will be able to:

1. Describe the Division of Medication Error Prevention and Analysis' role in pre-marketing and post-marketing activities to prevent and address medication errors.
2. Provide a brief overview of strategies aimed to increase the safe use of drug products by minimizing use error that is related to the design, naming, labeling, and/or packaging of drug products.
3. Provide examples of regulatory action taken to address recent medication errors.
4. Describe how you can help identify, prevent, and mitigate medication errors.

Target Audience
This activity is intended for physicians, physician assistants, nurses, pharmacists, pharmacy technicians, students, and other healthcare professionals.

Schedule

Time	Title	Lecturer(s)
Time: 1:00 PM to 2:00 PM	DDI Webinar Series: Ongoing Role of FDA in Medication Error Prevention	Mishale Mistry, PharmD, MPH

Continuing Education
The Food and Drug Administration, Center for Drug Evaluation and Research is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Food and Drug Administration – Center for Drug Evaluation and Research designates this live activity for a maximum of 1 *AMA PRA Category 1 Credit(s)*™. Physicians and Physician Assistants should claim only the credit commensurate with the extent of their participation in the activity.

The FDA-Center for Drug Evaluation and Research is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. (ACPE Universal Activity No. 0601-0000-17-084-L04-P and ACPE Universal Activity No. 0601-0000-17-085-L04-T). This program meets the criteria for 1 contact hour(s) of pharmacy education and pharmacy technician education.

This activity is a knowledge-based activity. These CE activities are primarily constructed to transmit knowledge (i.e., facts). The facts must be based on evidence as accepted in the literature by the health care professions.

FDA, Center for Drug Evaluation and Research is an approved provider of continuing nursing education by the Maryland Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.
This 1 contact hour Education Activity is provided by FDA, Center for Drug Evaluation and Research. Each nurse should claim only the time that he/she actually spent in the educational activity.

Requirements for receiving CE credit
Physicians, nurses, pharmacists, and pharmacy technicians, and those claiming non-physician CME: attendance is verified by Adobe Connect login or by a sign-in sheet, and completion of the final activity evaluation. Final activity evaluations must be completed within two weeks after the activity.

Pharmacists and Pharmacy Technician participants: partial credit cannot be awarded therefore you must attend the entire activity to receive CPE credit. No exceptions. Pharmacists and Pharmacy Technicians will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

Statements of Credit
Physicians and Nurses Statements of Credit for CE will be issued 10 weeks after the last session of this activity. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

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Disclosure
Faculty:
- Mishale Mistry, PharmD, MPH, Acting Associate Director, FDA/CDER/OSE/OMEPRM/DMEPA -nothing to disclose.

Planning Committee:
- Kara Burke, PharmD, Consumer Safety Officer, FDA/CDER/OCOMM/DDI-nothing to disclose
- Kimberly DeFronzo, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI-nothing to disclose
- Virginia Giroux, MSN, ARNP, CE Program Administrator, FDA/CDER/OEP/DLOD-nothing to disclose
- Lesley Navin, RN, MSN, Consumer Safety Officer, FDA/CDER/OCOMM/DDI-nothing to disclose
- Danielle Molnar, PharmD, Consumer Safety Officer, FDA/CDER/OCOMM/DDI – nothing to disclose
- Edward Weinstein, MD, Medical Officer, Office of New Drugs, Division of Anti-Infective Products-nothing to disclose

CE Consultation and Accreditation Team
- Justin Gorinson, CHES, ORISE Fellow, FDA/CDER/OEP/DLOD-nothing to disclose
- Karen Zawalick, CE Consultation and Accreditation Team Leader, FDA/CDER/DLOD-nothing to disclose

Registration Fees and Refunds
Registration is complimentary therefore refunds are not applicable.

Requirements for Certificate of Completion (Non CE)
Must attend 80% of the lectures (verified by a sign-in sheet).

References

- National Coordinating Council for Medication Error Reporting and Prevention. Available at: www.nccmerp.org. Accessed 12/30/2014
- Institute for Safe Medication Practices. Label characteristic contributes to errors. ISMP Med Saf Alert Acute Care. Jan 2016;21(1):2-3.
- ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2015. Available from: http://www.ismp.org/tools/errorproneabbreviations.pdf.
- Institute for Safe Medication Practices. Safety Briefs: Positive change, negative consequence. ISMP Med Saf Alert Acute Care. July 2014;19(15):1.
- Institute for Safe Medication Practices. Safety Briefs: QC for barcodes. ISMP Med Saf Alert Acute Care. March 2013;18(5):1-2.
- Institute for Safe Medication Practices. Safety Briefs: How NOT to barcode topical gels/creams. ISMP Med Saf Alert Acute Care. Feb 2016;21(3):4.
- Institute for Safe Medication Practices. Safety briefs. ISMP Med Saf Alert Community/Ambulatory Care. 2003;2(11):1-4.

- Institute for Safe Medication Practices. Durasal-Durezol mix-up illustrates how dangerous product problems persist long after recognition. ISMP Med Saf Alert Acute Care. 2011;16(19):1-3.
- Institute for Safe Medication Practices. Safety briefs: Enabling name confusion. ISMP Med Saf Alert Community/Ambulatory Care. 2013;12(5):1-3.
- Institute for Safe Medication Practices. Drug name suffix confusion is a common source of errors. ISMP Med Saf Alert Community/Ambulatory Care. 2003;2(4):1-4.
- Institute for Safe Medication Practices. Searching by drug name gives information on wrong drug. ISMP Med Saf Alert Acute Care. August 2002;17(16):3.
- Phonetic and Orthographic Computer Analysis (POCA) Program. http://www.fda.gov/Drugs/ResourcesForYou/Industry/ucm400127.htm
- FDA Drug Safety Communication. FDA requires label warnings to prohibit sharing of multi-dose diabetes pen devices among patients. 2015 Feb 25.
- FDA Drug Safety Communication. FDA approves brand name change for antidepressant drug Brintellix (vortioxetine) to avoid confusion with antiplatelet drug Brilinta (ticagrelor). 2016 May 6.
- FDA Drug Safety Communication. FDA cautions about dose confusion and medication error with antibacterial drug Avycaz (ceftazidime and avibactam). 2015 Sept 22.
- FDA Drug Safety Communication. FDA cautions about dosing errors when switching between different oral formulations of antifungal Noxafil (posaconazole). 2016 Jan 4.
- FDA Drug Safety Communication. FDA approves a dedicated syringe to be used with Humulin R U-500 insulin. 2016 Jul 8.
- Draft Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors. Food and Drug Administration. 2013. Available from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM349009.pdf
- Guidance for Industry: Safety Considerations for Product Design to Minimize Medication Errors. Food and Drug Administration. 2016. Available from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM331810.pdf
- Draft Guidance for Industry: Best Practices in Developing Proprietary Names for Drugs. 2014. Available from http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm398997.pdf

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