Activity Outline
DDI Webinar Series: Collaborating with FDA- Get Involved with FDA's MedWatch Adverse Reporting Program
February 7, 2017 1:00-2:00pm EST
Webinar

Description
This series of educational webinars are designed to aid Healthcare Professionals, Pharmacy, Nurse Practitioner, Physician Assistant and Medical students to provide better patient care by knowing how to find relevant FDA regulatory information that will improve drug safety. This webinar will give an overview of the Office of Health and Constituent Affairs, Identify ways to advance FDA messages and be involved in FDA processes, and describe how to report adverse events to FDA MedWatch, as well as obtain safety information.

References
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program http://www.fda.gov/Safety/MedWatch/default.htm
- MedWatchLearn http://www.accessdata.fda.gov/scripts/MedWatchLearn/
- MEDWATCH Consumer Voluntary Reporting (FORM FDA 3500B) http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf
- MedWatch Minute For Health Professionals http://www.fda.gov/Safety/MedWatch/ucm133050.htm
- FDA's response to IOM 2006 Report on The Future of Drug Safety – Promoting and Protecting the Health of the Public (2007) http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM171627.pdf
- FDA report to Congress – Changing the Future of Drug Safety: FDA Initiatives to Strengthen and Transform the Drug Safety System, July 2009 http://www.fda.gov/downloads/Safety/SafetyofSpecificProducts/UCM184046.pdf
- ISMP(Institute for Safe Medication Practices) website – FDA Safety Alerts at http://www.ismp.org/Tools/FDASafetyAlerts.asp
- ISMP QuarterWatch – Monitoring FDA MedWatch reports at http://www.ismp.org/quarterwatch/default.aspx
- National Patient Safety Foundation: Improving Root Cause Analyses and Actions to Prevent Harm at http://www.npsf.org/?page=RCA2

Series Objectives:
- Explain how to utilize FDA's drug information, medication safety resources, and regulatory guidances, to improve delivery of patient care and optimize outcomes.
- 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:

- Describe the FDA Office of Health and Constituent Affairs (OHCA)
- Identify ways to advance FDA messages and be involved in FDA processes
- Describe the FDA MedWatch Program.
- Identify the types of adverse events and product problems that should be reported to FDA.
- Explain how to submit a report to the FDA MedWatch Program.
- Summarize how to obtain safety information from FDA MedWatch.

Target Audience
This activity is intended for physicians, nurses, pharmacists, and pharmacy technicians.

Schedule

Time	Title	Lecturer(s)
Time: 1:00 PM to 2:00 PM	DDI Webinar Series: Collaborating with FDA- Get Involved with FDA's MedWatch Adverse Reporting Program	Teresa Rubio PharmD

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. 0601-0000-17-008-L05-P) and ACPE Universal Activity No. 0601-0000-17-009-L05-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:
- Teresa Rubio, PharmD, Health Programs Coordinator, FDA/CDER/OEXA/OHCA–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).

Initial Release Date: February 7, 2017