Activity Outline
FDA Drug Topics: An Overview of FDA's Expanded Access Program with a Focus on Individual Patient Expanded Access
February 20, 2018
FDA

Series 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 an orientation to drug information resources on the FDA website including drug shortages, recalls, adverse events reporting and drug labeling resources.

Lecture Description
This webinar will discuss and summarize FDA's expanded access program, including the three types of expanded access and requirements for requesting expanded access. We will also review the resources on expanded access available to patients and health care providers and will review and explain how a physician may submit a request for individual patient expanded access using Form FDA 3926.

References

- Guidance for Industry, Expanded Access to Investigational Drugs for Treatment Use - Questions and Answers: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm351261.pdf.
- Guidance for Industry, Individual Patient Expanded Access Applications: Form FDA 3926: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm432717.pdf.
- August 13, 2009 Final Rule on Expanded Access to Investigational Drugs for Treatment Use: https://www.federalregister.gov/documents/2009/08/13/E9-19005/expanded-access-to-investigational-drugs-for-treatment-use.

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, policy and regulatory changes which would impact prescribing and medication management to optimize patient care.

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

- Summarize the objectives of the FDA's expanded access program
- Identify the types of expanded access requests
- Describe the requirements for requesting expanded access
- Review web resources available for patients and healthcare professionals
- Explain how a physician may submit individual patient IND expanded access requests to the FDA using FDA Form 3926

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

Agenda

Lecture 1 February 20, 2018

Time	Topic	Speaker
1:00 - 2:00 PM	An Overview of FDA's Expanded Access Program with a Focus on Individual Patient Expanded Access	Colleen Locicero Deborah Miller, PhD, MPH, MSN, RN LINDSAY WAGNER, PharmD

Continuing Education Accreditation

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In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)* ™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-18-027-L04-P, and ACPE Universal Activity Number JA0002895-0000-18-027-L04-T for 1.00 contact hour(s).

CNE

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Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, pharmacist techs, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

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

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit. Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Locicero, Colleen, Associate Director for Regulatory Affairs, FDA/CDER/OND/ODE I - nothing to disclose
- Miller, Deborah, PhD, MPH, MSN, RN, Health Programs Coordinator, Food and Drug Administration - nothing to disclose
- WAGNER, LINDSAY, PharmD, Team Leader, FDA - nothing to disclose

Planning Committee

- Burke, Kara, PharmD, Pharmacist, FDA/CDER/OCOMM/DDI - nothing to disclose
- DeFronzo, Kimberly, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Navin, Lesley, RN, MSN, CSO, FDA/CDER/DDI - nothing to disclose
- Weinstein, Edward, M.D., Ph.D., Medical Officer, CDER FDA *My spouse received Salary from EndoCentre of Baltimore for a role as Employee.*

CE Consultation and the Accreditation Team

- Gorinson, Justin, B.S., CHES, ORISE Fellow, FDA/CDER/OEP/DLOD - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds
Registration is complimentary, therefore refunds are not applicable.