Activity Outline
FDA Drug Topics: Drug Shortages: FDA Efforts, Current Challenges and Future Goals
November 19, 2019
FDA

Activity Coordinator
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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.

Lecture Description
This activity will introduce the FDA's Drug shortage program, explain how the agency is addressing drug shortages and speak to the various challenges that lead to drug shortages.

References

- FDA Sixth Annual Report on Drug Shortages for Calendar Year 2018 https://www.fda.gov/media/130561/download
- FDA Shortages Additional News And information https://www.fda.gov/drugs/drug-shortages/drug-shortages-additional-news-and-information
- Federal Food, Drug, and Cosmetic Act (FD&C Act), Section 506C (21 USC 356c) https://www.gpo.gov/fdsys/pkg/USCODE-2012-title21/pdf/USCODE-2012-title21-chap9-subchapV-partA-sec356c.pdf
- Federal Register Final Rule, 80 FR 38915 (July 8, 2015), Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products. https://www.gpo.gov/fdsys/pkg/FR-2015-07-08/pdf/2015-16659.pdf. See also 21 CFR 310.306, 314.81, and 600.82.
- CDER MAPP 4190.1 Rev. 3, Drug Shortage Management (11/1995; Rev. 1, 9/2006; Rev. 2, 9/2014; Rev. 3, 11/2018): https://www.fda.gov/media/72447/download
- Executive Order 13588 (October 31, 2011), Reducing Prescription Drug Shortages: https://obamawhitehouse.archives.gov/the-press-office/2011/10/31/executive-order-13588-reducing-prescription-drug-shortages.

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:

- Identify what FDA can and cannot do to prevent and mitigate drug shortages
- Describe how to report a drug shortage to the FDA
- Summarize the pharmaceutical Industry’s role in drug shortage prevention and mitigation

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

Agenda

Lecture 1 November 19, 2019

Time	Topic	Speaker
1:00 - 2:00 PM	Drug Shortages: FDA Efforts, Current Challenges and Future Goals	LEO ZADECKY jin ahn, PharmD

Continuing Education Accreditation

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 JA0002895-0000-19-020-L04-P, and ACPE Universal Activity Number JA0002895-0000-19-020-L04-T for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

AAPA

This activity is designated for 1.00 AAPA Category 1 CME credits. PAs should only claim credit commensurate with the extent of their participation.

CPH

Up to 1.00 CPH Recertification Credits may be earned at this event.

Requirements for Receiving CE Credit

Physicians, physician assistants, 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.

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, physician assistants, 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

- ZADECKY, LEO, SR Program management officer, FDA/CDER/IO/DSS *May reference off-label use.*
- ahn, jin, PharmD, Senior Program Management Officer, FDA - nothing to disclose

Planning Committee

- Burke, Kara, PharmD, Team Leader/Pharmacist, FDA/CDER/OCOMM/DDI - nothing to disclose
- Cao, Christian, MPAS, PA-C, Safety Evaluator Team Leader, FDA/CDER/OSE/DPV - 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
- Kapoor, Rama, MD, M.D., Medical Officer, FDA - nothing to disclose
- Navin, Lesley, RN, MSN, Consumer Safety Officer, FDA/CDER/DDI - nothing to disclose

CE Consultation and Accreditation Team

- Lisa Thompson, MSHA, MBA, CE Consultant, 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.