Activity Outline
FDA Drug Topics: Biosimilar and Interchangeable Products in the U.S.: Scientific Concepts, Clinical Use, and Practical Considerations
December 10, 2018
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 webinar will provide an overview of biosimilar and interchangeable products and the approval process in the U.S. This webinar will explain the various scientific concepts used in the development of biosimilar products and the FDA's approval standards. In addition, we will describe some practical information regarding use of these products, such as labeling, terminology, and pharmacy substitution. This webinar will also review the resources available to health care professionals about biosimilar and interchangeable products.

References

- Biosimilars - https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/default.
- Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf
- Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291134.pdf

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:

- Explain the difference between biosimilar and interchangeable products and how they are prescribed/dispensed.
- Describe the general components of the labeling for biosimilar products and the value of labeling to provide the product's safety and effectiveness information to health care providers.
- Identify the terminology used to describe various aspects of biosimilar and interchangeable products, and the development and approval process.
- Explain the goals of a standalone and biosimilar development pathways and the stepwise evidence approach used to generate data in support of a demonstration of biosimilarity.
- Recognize the importance of the analytical foundation and how FDA assesses analytical similarity.
- Describe the resources available to health care professionals about biosimilar and interchangeable products.

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

Agenda

Lecture 1 December 10, 2018

Time	Topic	Speaker
1:00 - 2:00 PM	Biosimilar and Interchangeable Products in the U.S.: Scientific Concepts, Clinical Use, and Practical Considerations	Leah Christl, Ph.D. Sue Lim, MD

Continuing Education Accreditation

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IPCE CREDIT™

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

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

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.

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

- Christl, Leah, Ph.D., Associate Director for Therapeutic Biologics, Office of New Drugs, CDER, FDA - nothing to disclose
- Lim, Sue, MD, Director of the Scientific Review Staff, FDA/CDER/IO/TBBS - nothing to disclose

Planning Committee

- Burke, Kara, PharmD, Team Leader/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 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.