Activity Outline
FDA Drug Topics: Biosimilar and Interchangeable Biological Products: Basic Concepts and Practical Resources
December 17, 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 webinar will provide a brief introduction to the scientific concepts behind biologics and the scientific and regulatory basis for the biosimilar pathway. The webinar will build on past biosimilar webinars and further explores into the science of biological molecules, including size, complexity, and structure. In addition, we will review practical information regarding the use of these products, such as labeling, terminology, pharmacy substitution, and the Purple Book resource that is available to health care professionals.

References

- FDA website https://www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval Purple
- Book: https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or
- Gramer MJ, “Product quality considerations for mammalian cell culture process development and manufacturing.” Adv Biochem Eng Biotechnol 2014, 139:123-166
- Liu L, “Antibody glycosylation and its impact on the pharmacokinetics and pharmacodynamics of monoclonal antibodies and Fc-fusion proteins.” J Pharm Sci 2015, 104:1866-1884
- 5. Hmiel LK, Brorson KA, Boyne MT, “Post-translational structural modifications of immunoglobulin G and their effect on biological activity.” Anal Bioanal Chem 2015, 407:79-94
- 6. Berkowitz SA, Engen JR, Mazzeo JR, Jones GB, “Analytical tools for characterizing biopharmaceuticals and the implications for biosimilars.” Nat Rev Drug Disc. July 2012; 11:527-540

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:

- Describe how biologics differ from small molecules
- Explain why some biologics cannot be copied exactly
- Compare and contrast the development and approval process for new biologics and biosimilars/interchangeables
- Recognize the differences in the statutory requirements for approval between new biologics and biosimilars or interchangeables
- Describe and explain the resources available for health care provider to learn more about biosimilar and interchangeable products through the enhanced Purple Book

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

Agenda

Lecture 1 December 17, 2019

Time	Topic	Speaker

1:00 - 2:00 PM	Biosimilar and Interchangeable Biological Products: Basic Concepts and Practical Resources	Sarah Yim, MD Leila Hann

Continuing Education Accreditation

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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

- Hann, Leila, Science Policy Analyst, FDA - nothing to disclose
- Yim, Sarah, MD, Acting Director, Office of Therapeutic Biologics and Biosimilars - 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.