Activity Outline
FDA Drug Topics: Biosimilar and Interchangeable Biosimilars: Review of Scientific Concepts, Case Studies, and Resources
January 25, 2022
FDA

Activity Coordinator:
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Description

This webinar will provide an intermediate overview of the scientific and regulatory basis for the biosimilar and interchangeable biosimilar approval pathway. The webinar will build on past biosimilar webinars and further explores the science of biological molecules, including size, complexity, and inherent variation. In addition, we will discuss the use of these products, including labeling, terminology, and pharmacy substitution. To enhance understanding, we will review case studies to highlight the data that can support biosimilarity and interchangeability. This webinar will also demonstrate the functionality of resources available to health care professionals such as the Purple Book Database.

This activity may reference off-label use of FDA-approved products.

References

- Purple Book: Database of Licensed Biological Products: https://purplebooksearch.fda.gov/
- Cohen, H.P., Blauvelt, A., Rifkin, R.M. et al. "Switching Reference Medicines to Biosimilars: A Systematic Literature Review of Clinical Outcomes." Drugs 78, 463–478 (2018). https://doi.org/10.1007/s40265-018-0881-y
- Datta-Mannan. "Mechanisms Influencing the Pharmacokinetics and Disposition of Monoclonal Antibodies and Peptides." CPT Pharmacometrics Syst Pharmacol. 2017;6(9):576-588. doi:10.1002/psp4.12224
- Walsh, G. "Biopharmaceutical benchmarks 2018." Nat Biotechnol 36, 1136–1145 (2018). https://doi.org/10.1038/nbt.4305
- Guidance for Industry: Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products. November 2019. https://www.fda.gov/media/133014/download
- Oncology Drugs Advisory Committee meeting on October 10, 2018. Meeting materials: https://www.fda.gov/advisory-committees/advisory-committee-calendar/meeting-oncologic-drugs-advisory-committee-10102018-10102018#event-materials

Learning Objectives

- Describe how biologics differ from small molecules (size, complexity, inherent variation) and explain why some biologics cannot be copied exactly.
- Compare and contrast the development, statutory requirements, and approval process for new biologics and for biosimilars/interchangeables.
- Differentiate between the requirements for FDA approval of generics and biosimilars/interchangeables and discuss the availability of insulin products.
- Review case studies of approved biosimilar and interchangeable products.
- Summarize the new resources available for health care providers and faculty to learn more about biosimilar and interchangeable products and how to use the Purple Book Database of Licensed Biological Products.

Target Audience
This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, Certified Public Health Professionals (CPH), and physician assistants.

Agenda
Day 1 January 25, 2022

Time	Topic	Speaker
1:00 - 2:00 PM	FDA Drug Topics: Biosimilar and Interchangeable Biosimilars: Review of Scientific Concepts, Case Studies, and Resources	Nina Brahme, PhD, MPH Sarah Ikenberry, MA Shelley Skibinski, 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 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 UAN JA0002895-0000-22-005-L03-P, and ACPE Universal Activity Number UAN JA0002895-0000-22-005-L03-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. FDA Center for Drug Evaluation and Research has been authorized by the American Academy of PAs (AAPA) to award AAPA Category 1 CME credit for activities planned in accordance with AAPA CME Criteria. 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.

Attention Pharmacists and Pharmacy Techs: Failure to provide your correct NABP AND Date of Birth information, in the required format, may result in the loss of credit for this activity. NABP profile number should be the 6-7 digit profile number assigned by the CPE Monitor and your birth date should be in the MMDD format (e.g. 0721) Do not provide your pharmacy license number. Please click the "My Account" tab and then navigate to "Edit Contact Information" to verify that your information is correct.

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 8 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Brahme, Nina, PhD, MPH, Clinical Analyst, Food and Drug Administration - *nothing to disclose*
- Ikenberry, Sarah, MA, Health Communication Specialist, CDER/OND/OTBB - *nothing to disclose*
- Skibinski, Shelley, PharmD, Project Coordinator, FDA/CDER/OND/OTBB - *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*
- PARAOAN, DIANNE, MPH, RN, Associate Director for Regulatory Affairs, FDA/ CDER/ OMP - *nothing to disclose*
- Rama, Kapoor, MD, Medical Officer, FDA - *nothing to disclose*

CE Consultation and Accreditation Team

- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

All of the relevant financial relationships listed for these individuals have been mitigated.

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

Requirements for Certificate of Completion (Non CE)
Must attend 100% of the activity.