Activity Outline
FDA Grand Rounds: One Health at FDA: From Concept to Application
July 14, 2022
Virtual

Activity Coordinators:
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Series Description
The FDA Grand Rounds is webcast monthly to highlight cutting-edge research underway across the agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities.

Lecture Description
The One Health concept works at the interconnection of three domains: human, animal, and environmental health. One Health presents a more holistic view of the U.S. Food and Drug Administration's (FDA) mission. The FDA's efforts to improve health go beyond recognizing disease transmission through an isolated lens of human health and acknowledge human-animal interactions and associated environmental factors. The One Health concept's convergence already exists in the FDA's mission statement when considering the Agency's responsibilities and authorities. The Agency fulfills its mission to benefit both people and animals by ensuring the safety and efficacy of regulated products such as food or feed, drugs, devices, and human biologics. It regulates the manufacturing, marketing, and distribution of regulated products to ensure that safety and quality standards are met that benefit both people and animals. The Agency utilizes a multidisciplinary and multisectoral approach to gathering data that enhances more informed, evidence-based regulatory decisions when establishing standards and guidance. Last but not least, FDA coordinates regulatory pathway measures fostering the advancement of medical countermeasures that diagnose, prevent, protect, and treat conditions derived from intentional or unintentional emerging threats for chemical, biological, radiological, or nuclear materials. These threats hold no boundaries and can adversely impact people and animals alike. This presentation will describe the One Health concept and how it applies to FDA's regulatory mission. It will also explain FDA's application of the One Health concept in its regulatory activities.

References
- U.S. Food and Drug Administration (2021). 2021 Advancing Regulatory Science at FDA: Focus Areas of Regulatory Science (FARS) - https://www.fda.gov/news-events/fda-brief/fda-brief-fda-publishes-report-fo cus-areas-regulatory-science
- Berthe,Franck Cesar Jean; Bouley,Timothy; Karesh,William B.; Le Gall,Francois G.; Machalaba,Catherine Christina; Plante,Caroline Aurelie; Seifman,Richard M. Operational framework for strengthening human, animal and environmental public health systems at their interface (English). Washington, D.C.: World Bank Group. http://documents.worldbank.org/curated/en/703711517234402168/Operational-fr amework-for-strengthening-human-animal-and-environmental-public-health-syst ems-at-their-interface
- Lebov J, Grieger K, Womack D, Zaccaro D, Whitehead N, Kowalcyk B, MacDonald PDM. A framework for One Health research. One Health. 2017 Mar 24;3:44-50. doi: 10.1016/j.onehlt.2017.03.004. https://pubmed.ncbi.nlm.nih.gov/28616503/

Series Objectives
- Discuss the research conducted at the FDA
- Explain how FDA science impacts public health

Learning Objectives After completion of this activity, the participant will be able to:
- Describe the One Health concept.
- Examine how FDA applies the One Health concept in its activities.
- Explain how FDA's application of the One Health concept has national and international reach.
- Discuss some One Health challenges.
- Explore what the future may look like as FDA adopts a One Health approach.

Target Audience
This activity is intended for physicians, pharmacists, nurses, and other scientists within the agency external scientific communities.

Agenda

Lecture 1 July 14, 2022

TIME	TOPIC	SPEAKER
12:00 - 1:00 PM EDT	One Health at FDA: From Concept to Application	Brianna Skinner, DVM Annamaria Castiglia, DVM

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IPCE CREDIT™

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.

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CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-22-006-L04-P 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, 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 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
- Castiglia, Annamaria, DVM, One Health Coordinator, CVM - *nothing to disclose*
- Skinner, Brianna, DVM, Senior Regulatory Veterinarian, Office of Counterterrorism & Emerging Threats - *nothing to disclose*

Planning Committee
- Dinatale, Miriam, Team Leader, Food and Drug Administration - *nothing to disclose*
- Pfundt, Tiffany, PharmD, Senior Advisor, HHS/ASPR - *nothing to disclose*
- Wheelock, Leslie, RN, MS, Director, OSPD, FDA, OC, OCS, OSPD - *nothing to disclose*

CE Consultation and Accreditation Team
- Bueide, Rachel E., MPhil, Training Specialist, FDA/CDER/OEP/DLOD - *nothing to disclose*
- 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.