Activity Outline
FDA Grand Rounds: Challenges in Predicting the Environmental Exposure Concentration of Terrestrial Animal Drugs
February 10, 2022
Virtual

Activity Coordinator:
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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
As part of the environmental review process under the National Environmental Policy Act (NEPA), the Center for Veterinary Medicine (CVM) determines the exposure concentration for proposed new animal drugs in the environment. Due to the complexity of estimating these concentrations for the various environmental conditions in the US, CVM has developed an environmental fate model, VETPEC, which uses animal characteristics, spatially and temporally variable data, and modern scientific principles to calculate daily environmental concentrations of animal drugs. This seminar will highlight CVM's environmental review process with a focus on the exposure assessment.

References

- Spaepen, K.R.I., et al., A uniform procedure to estimate the predicted environmental concentration of the residues of veterinary medicines in soil. Environmental Toxicology and Chemistry, 1997. 16(9): p. 1977-1982.
- Young, D., Pesticide in Water Calculator (PWC). 2016, United States Environmental Protection Agency: Washington, DC.
- USFDA. "Environmental Impact Assessments (EIA) for Veterinary Medicinal Products (VMP) - Phase I." 2001. https://www.regulations.gov/docket?D=FDA-1999-D-3541
- USFDA. " Environmental Impact Assessments (EIA) for Veterinary Medicinal Products (VMP) - Phase II." 2006. https://www.regulations.gov/docket?D=FDA-2004-D-0273

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:

- Identify the methods CVM uses to evaluate the potential for environmental impacts
- Describe the challenges of estimating concentrations of animal drugs in the varying United States environments.
- Examine the tools developed to estimate environmental concentrations of new animal drugs.

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

Agenda

Lecture 1 February 10, 2022

Time	Topic	Speaker
12:00 - 1:00 PM	Challenges in Predicting the Environmental Exposure Concentration of Terrestrial Animal Drugs	Andrew Miglino, PhD

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 JA0002895-0000-22-006-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

- Miglino, Andrew, PhD, Physical Scientist, FDA/CVM - *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.