

Activity Outline
FDA Grand Rounds: Cyclospora cayetanensis: The crossroads between the scientific advances and knowledge gaps
June 13, 2019
WO Building 32 - Room 1243

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

In recent years, *Cyclospora cayetanensis* has emerged globally as a significant foodborne pathogen, causing a diarrheal illness called cyclosporiasis. In the US, *C. cayetanensis* has caused large and complex outbreaks, which in the past, were mainly linked to consumption of imported fresh produce such as cilantro. In 2018, multiple outbreaks of cyclosporiasis linked to different produce items were identified. The total number of outbreak cases was higher than in previous years, with a total of 2,299 laboratory-confirmed, domestically acquired cases of cyclosporiasis reported from 33 states. The two major cyclosporiasis outbreaks investigated in 2018 were linked to fresh produce vegetable trays produced by Del Monte and a variety of salads sold at McDonald's restaurants. During the 2018 investigations, both imported and domestic fresh produce samples were tested for the presence of *Cyclospora cayetanensis* using a validated laboratory method. These analyses confirmed the presence of the parasite in domestic and imported fresh produce. This was the first time in many years, that FDA has used a validated method to detect *C. cayetanensis* in foods in support of surveillance assignments and outbreak investigations. This lecture will discuss the recent scientific advances that impacted the outcomes of the investigations of cyclosporiasis outbreaks in 2018 and the scientific gaps that still represent major public health and regulatory challenges for the FDA.

References

- Guo Y, Roellig DM, Li N, et al. Multilocus Sequence Typing Tool for *Cyclospora cayetanensis*. *Emerg Infect Dis.* 2016;22(8):1464-7.

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 main foodborne parasites of regulatory significance for the FDA's mission in food safety
- Summarize the Life Cycle of *Cyclospora cayetanensis*
- Distinguish the specific steps that comprise the BAM Chapter 19B method used by the FDA to detect *Cyclospora cayetanensis* in fresh produce.
- List the research areas that CFSAN is prioritizing to address the regulatory and public health issues associated with *Cyclospora cayetanensis*.
- Identify the scientific advances in *Cyclospora cayetanensis* research that were relevant for the FDA's mission in food safety.
- Identify the significant challenges that represent hurdles to advance in *Cyclospora cayetanensis* research.

Target Audience

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

Agenda

Lecture 1 June 13, 2019

Time	Topic	Speaker
12:00 - 1:00 PM	<i>Cyclospora cayetanensis</i> : The crossroads between the scientific advances and knowledge gaps	Alexandre DaSilva, D.Sc

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 1.00 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 JA0002895-0000-19-012-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.

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

- ▣ DaSilva, Alexandre, D.Sc, SBRS Research Microbiologist Lead Parasitologist, US Food and Drug Administration - nothing to disclose

Planning Committee

- ▣ Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- ▣ KEMPF, LUCAS, MD - nothing to disclose
- ▣ Lee, Christine, PharmD, , PhD, General Health Scientist, FDA - nothing to disclose
- ▣ Wheelock, Leslie, MS, RN, Director, OSPD, FDA, OC, OCS, OSPD - nothing to disclose

CE Consultation and Accreditation Team

- ▣ Bryant, Traci, M.A.T., 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.