

Science and Regulation of Live Microbiome-based Products Used to Prevent, Treat, or Cure Diseases in Humans

AGENDA

NIAID Conference Center
5601 Fishers Lane, Rm. 1D13
Rockville, MD 20852

September 17, 2018

Time	Topic	Speaker
9:00 - 9:10 AM	Welcome Introductory remarks	Carolyn Deal, NIAID Peter Marks, CBER
Keynote Address <i>Introduction: Paul Carlson (OVR, CBER, FDA)</i>		
9:10 - 9:50 AM	The microbiome in human health and disease: A clinician-scientist's perspective	Vince Young, Univ. Michigan Medical School
9:50-10:00 AM	Qs and As	
Session 1: Regulatory Framework for "Probiotics" and Live Microbiome Based Products <i>Moderator: Theresa Finn (OVR, CBER, FDA)</i>		
10 - 10:15 AM	Dietary supplements containing probiotics	Bob Durkin, CFSAN, FDA
10:15 - 10:30 AM	Live microbiome-based products used to prevent, treat, or cure diseases in humans	Sheila Dreher-Lesnack, OVR, CBER, FDA
10:30-10:40	Clarifying Qs and As	
10:40 - 11:00 AM	BREAK	
Session 2: Safety and Effectiveness of Live Microbiome-based Products Used to Prevent, Treat, or Cure Diseases in Humans: Part 1 <i>Moderator: Susan McCune (OPT, FDA)</i> <i>Prevention of necrotizing enterocolitis</i>		
11:00 - 11:15 AM	Use of commercially available products to prevent NEC	Josef Neu, Univ. Florida
<i>Prevention of diarrhea</i>		
11:15 - 11:30 AM	The evidence is in for probiotics to prevent AAD: What is holding up evidence-based use in the USA?	Dan Merenstein, Georgetown Univ.
11:30 - 11:45 AM	Use of probiotics in acute pediatric gastroenteritis – Two large North American clinical trials	Stephen Freedman, Univ. Calgary
11:45 - 11:55 AM	Clarifying Qs and As	
11:55 - 1:00 PM	LUNCH	

Time	Topic	Speaker
Safety and Effectiveness of Live Microbiome-based Products Used to Prevent, Treat, or Cure Diseases in Humans: Part 2 Moderator: Paul Carlson (OVRR, CBER, FDA)		
<i>Prevention of C. difficile infection</i>		
1:00 - 1:15 PM	Use of commercially available products to prevent <i>C. difficile</i>	Krishna Rao, Univ. Michigan
1:15 - 1:30 PM	Overview of controlled studies using FMT for prevention of <i>C. difficile</i> infection	Colleen Kelly, Brown Univ.
1:30 - 1:45 PM	CMC considerations for live microbiome-based product development	John Aunins, Seres
1:45 - 1:55 PM	Clarifying Qs and As	
1:55 - 2:45 PM	Panel Discussion	
2:45 - 3:00 PM	BREAK	
Session 3: Strain Selection for Live Microbiome-Based Products to Prevent, Treat, or Cure Diseases in Humans Moderator: Ryan Ranallo (NIAID, NIH)		
3:00 - 3:15 PM	Drugs based on rationally defined bacterial consortia	Bernat Olle, Vedanta Biosciences
3:15 - 3:30 PM	Development of defined consortia for recurrent <i>C. difficile</i> infection	Elaine Petrof, Queens University
3:30 - 3:45 PM	Finding the needle in the haystack: Moving from consortia to single strains	Neil Surana, Duke University School of Medicine
3:45 - 4:00 PM	<i>Bacteroides fragilis</i> used in a mouse model of autism	Greg Bates, Axial Biotherapeutics
4:00 - 4:15 PM	<i>L. plantarum</i> to prevent sepsis: Timing and Strains Matter	Pinaki Panigrahi, Nebraska Med Center
4:15-4:30 PM	Clarifying Qs and As	
4:30 - 5:15 PM	Panel Discussion	
5:15 - 5:30 PM	Wrap up	Carolyn Deal, NIAID, NIH