

2024 ADUFA V Education Conference July 17, 2024

July 17, 2024

9:00 am EDT

Docket No. FDA-2024-N-2602

[Regulations.gov](https://www.regulations.gov)

9:00 Opening Remarks

Dr. Walt Ellenberg
Dr. Robert Califf
Dr. Matt Lucia

Overview of New Animal Drug Approval Process

9:30 INAD to NADA
Elizabeth Hasbrouck

10:15 Break

10:30 Communication Pathways with CVM
Annie Roa

11:05 Best Practices in the Approval Process
Ana Lazo
Delisa Davis

11:40 Q&A on the General Approval Process
Walt Ellenberg & CVM Panel

12:00 Lunch

**1:00 Target Animal Safety Technical Section Overview,
Target Animal Effectiveness**
Dr. Prajwal Regmi

1:25 Clinical Pharmacology
Dr. Mark Heit

1:35 TAS & Effectiveness Best Practices
Dr. Cheryl Johnson

2:00 TAS & Effectiveness Hot Topics
Dr. Andrew Fidler

- 2:10** **Chemistry, Manufacturing and Controls Technical Section Overview**
Peter Bryk
- 2:40** **Break**
- 2:55** **Human Food Safety Technical Section Overview**
Dr. Jonathan Greene, Dr. Kimon Kanelakis,
and Dr. Heather Harbottle
- 3:30** **Environmental Impact Technical Section Overview**
Dr. Holly Zahner
- 4:00** **Minor Technical Section All Other Information, and Freedom of Information Summary, Labeling**
Dr. Ann Stohlman
Dr. Suzanne Sechen
- 4:30** **Q&A Session on Technical Sections**
Walt Ellenberg & CVM Panel
- 4:58** **Closing Remarks**
Walt Ellenberg, Moderator, CVM