Bioavailability Studies Submitted in NDAs and INDs – General Considerations

Ethan Stier, Ph.D., RPh

Associate Director for Lifecycle Management

Office of Clinical Pharmacology, FDA

Scope of Guidance

Included:

- BA Studies conducted in INDs and NDAs

Not Included:

Generics

- *Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA (August 2021)*

Scope of Guidance Cont.

Not Included:

Biosimilars

- *Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product (December 2016)*

Regulatory History Highlights

2003:

- First guidance published

2014:

- Revised guidance published for public comment
- Recommendations for BE studies for Generics published in separate guidance

Regulatory History Highlights cont.

2014:

- Endogenous substance
- Highly variable drugs
- Expanded MR Section
- NTI Section
- Added alcohol dose dumping section

Regulatory History Milestones and Highlights cont.

2019:

- draft version was published

2022:

- Addressed the public comments and guidance was finalized

Agenda

Bioavailability Studies Submitted in NDAs and INDs – General Considerations

by Dakshina Chilukuri, Ph.D.

Bioavailability Determination: Special Topics

by Dr. Jayabharathi Vaidyanathan, Ph.D.

Agenda (cont'd)

Relative Bioavailability: Pharmacodynamic and Non-Traditional Endpoints

by Dr. Kofi A. Kumi, Ph.D., R.Ph.

Recommended In Vitro Studies

by Dr. Okponanabofa Eradiri, Ph.D.