New Approach Method (NAMs) Priorities for the Human Foods Program

Steven M. Musser, Ph.D.

Associate Commissioner for Human Foods Research

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Commitment to Advancing the Development and Regulatory Use of NAMs

FDA

- HFP has a long-standing commitment to promote the development and use of new technologies to evaluate and predict the safety of regulated products.

- HFP has a broad research program aimed at developing NAMs for regulatory use. This includes, work done in our laboratories, collaborations across government agencies and working directly with developers.

- HFP has identified several top priorities for NAMs development based on historical actions.
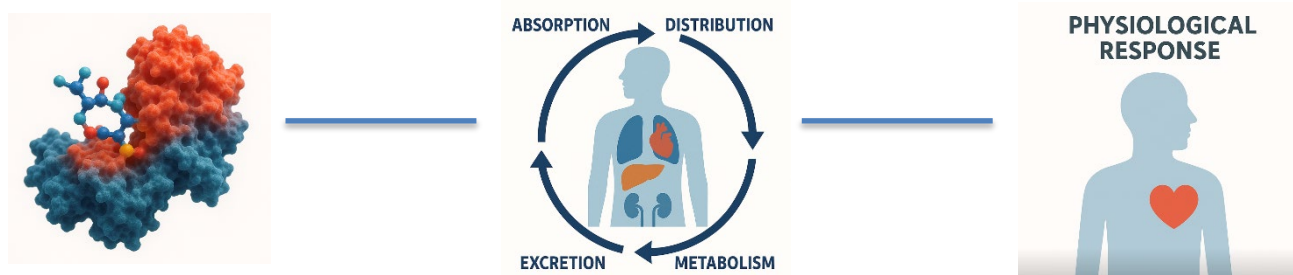
Advancing New Alternative Methodologies at FDA

SCAN ME

Human Foods Program Regulatory Space

FDA

Contrast to Medical Product Centers

- Authorities

- Postmarket vs Premarket

- Chronic vs. Acute toxicity issues

- Variable exposure vs. Steady state

- Mixtures vs. Single component

17%

83%

- Premarket
- Post Market
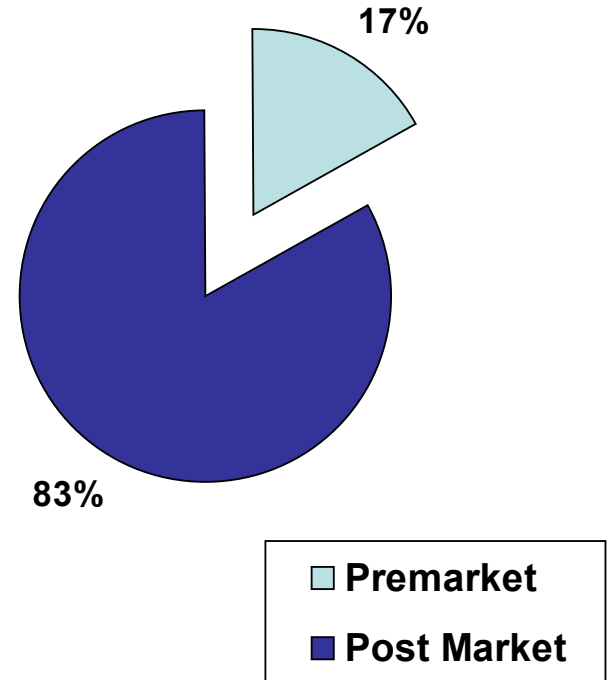
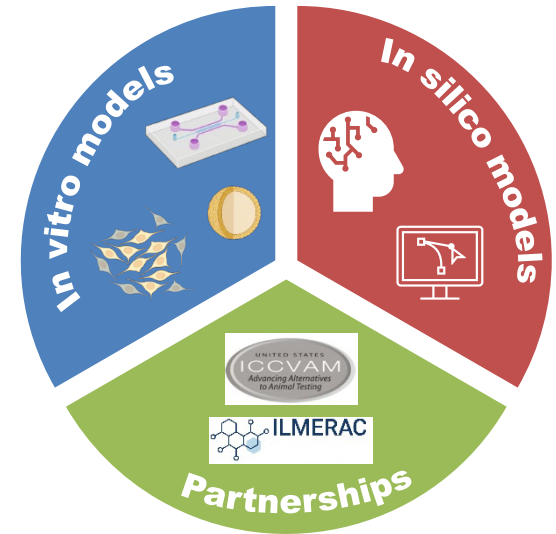# Foods / Drugs – Different Approaches

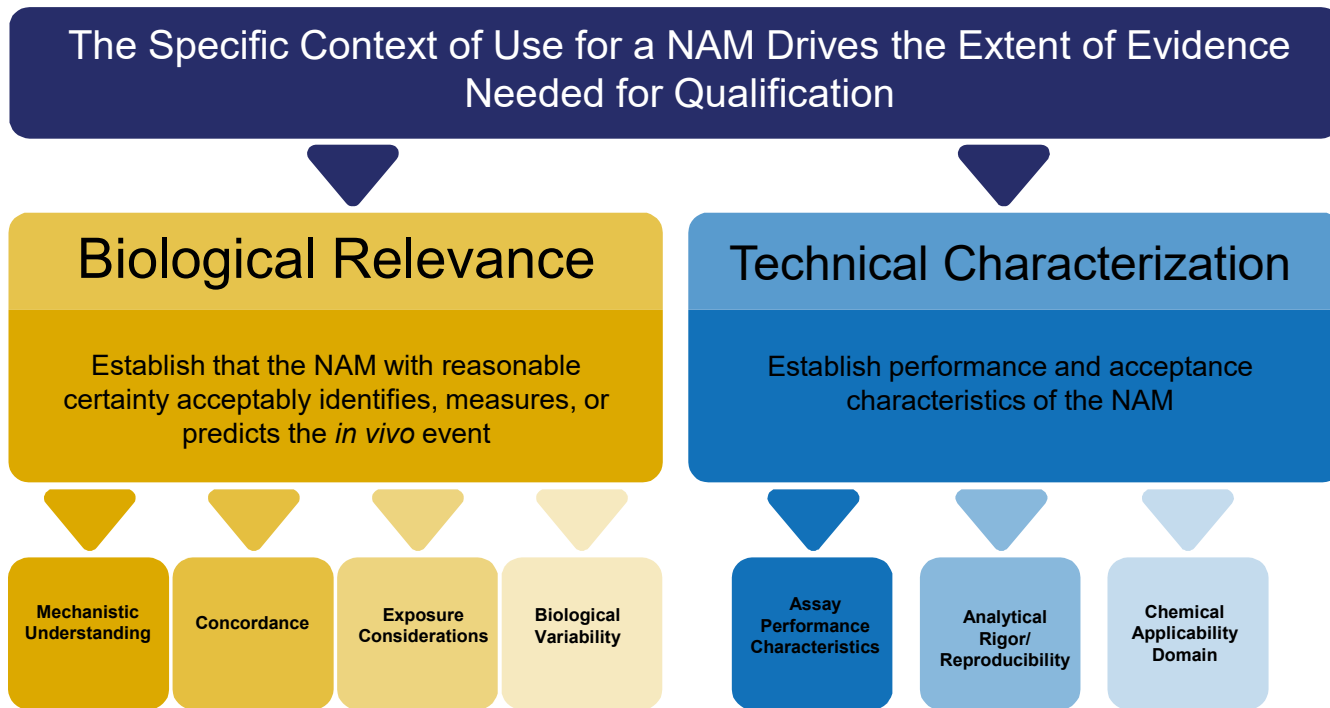Specific Pathway or target

Context of use   Context of toxicity

HFP Priorities on NAMs

- Specific HFP priorities:

  – Evaluate new technology/approaches
    - Focus areas – Developmental Neurotoxicity, Vascular Cardiotoxicity and Hepatotoxicity
  – Develop *in silico* approaches (QSAR, read across, etc.)
  – Intersection of diet, gut microbiome and chronic disease
  – Develop partnerships to enhance in-house research
  – Global activities

Scientific and Analytical Criteria for Acceptance for New Approach Methods for Food Chemicals

The Specific Context of Use for a NAM Drives the Extent of Evidence Needed for Qualification

Biological Relevance

Establish that the NAM with reasonable certainty acceptably identifies, measures, or predicts the *in vivo* event

- Mechanistic Understanding
- Concordance
- Exposure Considerations
- Biological Variability

Technical Characterization

Establish performance and acceptance characteristics of the NAM

- Assay Performance Characteristics
- Analytical Rigor/ Reproducibility
- Chemical Applicability Domain

Relevance!

- Reproducibility, ruggedness and cost

- More than hazard identification

- Predictive of *in vivo* effects

- Do the results account for relevant PBPK and exposure estimates

- Translatable to human

Thank you!

U.S. FOOD & DRUG ADMINISTRATION

Steven M. Musser

Email: Steven.Musser@fda.hhs.gov