**12.1.21**

**1. Modernize Toxicology to Enhance Product Safety**

**1**.1. Develop better models of human and animal (where applicable) adverse response

1.2. Identify and evaluate biomarkers and endpoints that can be used in non-clinical and clinical evaluations

1.3. Develop and Use computational methods and in silico modeling

**2. Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve** Product Development and Patient Outcomes

2.1. Develop and refine clinical trial designs, endpoints and analysis methods

2.2. Leverage existing and future data

2.3. Identify and qualify biomarkers and study endpoints

2.4. Facilitate Antimicrobial Drug Development and Address Antimicrobial Drug Resistance

2.5. Facilitate Drug Development and Appropriate Use for Patients with Serious Mental Illness.

2.6. Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve Outcomes in Diverse Populations

2.7. Immuno-oncology

2.8. Cell /Gene and Personalized Neo-antigen-based Therapies for Cancer

2.9. Health Equity and special populations in oncology drug development

2.10. Oncology trial designs, end points and statistical methodologies

2.11. Pediatric Oncology

2.12. Precision Oncology

**3. Support New Approaches to Improve Product Manufacturing and Quality**

3.1. Enable development and evaluation of novel and improved materials and manufacturing methods

3.2. Develop new analytical and in vitro release methods

3.3. Develop assessment tools to support facility and product surveillance and monitoring of quality systems and processes.

3.4. Reduce risk of microbial contamination of products

3.5. Improve scientific approaches to evaluate generic drugs

3.6. Identify and Qualify Biomarkers that are Associated with Therapeutic Response in Animals

3.7. Develop a Regulatory Database for Species Identification

3.8. Develop methods to improve the cybersecurity of medical devices

**4. Ensure FDA Readiness to Evaluate Innovative Emerging Technologies**

4.1. Develop assessment tools for novel therapies

4.2. Evaluate technologies designed to reduce nonmedical use and overdose involving opioids and other medications with abuse potential.

4.3. Evaluate drug safety in pediatric populations, which requires sources and methods for accurately measuring exposure (i.e. drug utilization) and outcomes.

4.4 Develop and facilitate innovative technologies toward universal pathogen reduction of the blood supply

**5. Harness Diverse Data through Information Sciences to Improve Health Outcome**

5.1. Develop and apply simulation models for product life cycles, risk assessment, and other regulatory science uses

5.2. Develop and analyze large scale clinical and nonclinical data sets

5.3. Computer Modeling and Simulation to Assess Product Risk

5.4. Collect and use patient input in regulatory decision-making

5.5. Systems Modeling of the Opioid Crisis

5.6. Longitudinal Data to Study Trajectory of Substance Use Disorders.

5.7. Oncology Patient-Focused Drug Development

5.8. Oncology Safety

5.9. Rare Cancers

5.10. Other Rare Diseases

5.11. Oncology Real World Data (RWD) Utilization

5.12. Harness Diverse Data to Improve Health Outcomes in Diverse Populations

**6. Implement a New Prevention-Focused Food Safety System to Protect Public Health**

6.1. Establish and implement centralized planning and performance measurement processes

6.2. Maintain mission critical science capabilities

**7. Facilitate Development and Availability of Medical Countermeasures (MCMs) to Protect Against Threats to U.S. and Global Health and Security**

7.1. Develop, characterize, and qualify tools to support MCM development under the Animal Rule or Accelerated Approval2

7.2. Modernize tools to evaluate MCM product safety, efficacy, and quality; and secure the MCM supply chain

7.3. Advance the development of tools to enable the rapid development and availability of investigational MCMs

**8. Strengthening Social and Behavioral Science at FDA by Enhancing Audience Understanding**

8.1. Assess awareness and understanding of FDA communications, especially among diverse audiences and populations, and identify methods to improve the comprehension of content, including numerical information

8.2. Explore ways that FDA communications can best complement those communicated by industry and other organizations to enhance audience comprehension

8.3. Assess public understanding of regulatory terms

8.4. Evaluate timing of release of recall or warning messages, how and when these messages can enhance impact, and how to communicate the end of a recall or warning.

8.5. Studies to increase the safety of post-approval drug use

8.6. Studies to evaluate the safety of approved drug products

8.7. Informing and Enhancing Audience Understanding Among Diverse Populations

**9. Strengthening the Global Product Safety Net**

9.1. Advancing Global Public Health

9.2. Analyzing and Utilizing Global Data to Manage Risks

9.3 Drug Shortages