

# UPDATE FROM THE FDA CENTER FOR TOBACCO PRODUCTS



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# USING OUR REGULATORY AUTHORITY

- Understand the regulated products
- Restrict product changes to protect public health
- Prohibit modified risk claims that state/imply reduced exposure or risk without an order
- Restrict marketing and distribution to protect public health
- Decrease the harms of tobacco products
- Ensure industry compliance with FDA regulation through education, inspections, and enforcement
- Educate the public about FDA's regulatory actions
- Expand the science base for regulatory action and evaluation

# CTP STRATEGIC PRIORITIES

- Product Standards
- Comprehensive FDA Nicotine Regulatory Policy
- Pre- & Post-Market Controls: Regulations & Product Reviews
- Compliance and Enforcement
- Public Education

# PRODUCT STANDARDS: IMPLEMENTING ONE OF THE LAW'S MOST POWERFUL TOOLS

- Advancing a product standard strategy that yields strong standards to improve public health
- Exploring potential standards for:
  - Addictiveness
  - Toxicity
  - Appeal



# INFORMING PRODUCT STANDARDS – NCTR\*

**E07548.01** - High-Throughput Screening Tobacco Constituents for Addiction Potential Using Docking of Nicotinic Acetylcholine Receptors (Hong, H; Orr, M)

**E07549.01** - Evaluating the Toxicity and Inflammation Produced by Cigarette Smoke Using Human In Vitro Airway Models (Cao, X; Healy, S; Chemerynski, S)

**E07568.01** - Microbial Populations and the Development of Tobacco Specific Nitrosamines in Moist Snuff Products (Foley, S; Koenig, M)

**E07525.01** - Pharmacokinetic Analysis of NNK in Sprague-Dawley Rats (Hu, S; Yeager, R; Rosenfeldt, H)

**E07531.01** - 13-Week Nose-Only Inhalation Toxicity Study of NNK in Rats (Hu, S; Yeager, R; Rosenfeldt, H)



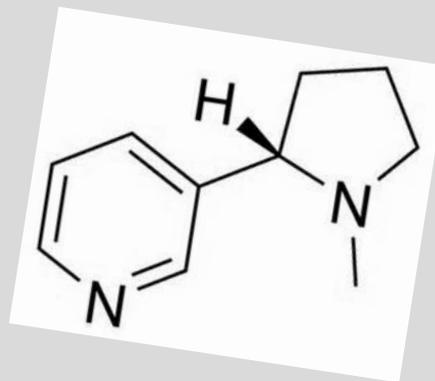
# COMPREHENSIVE FDA NICOTINE REGULATORY POLICY: LOOKING AT NICOTINE DIFFERENTLY

- Establish an integrated, FDA-wide policy on nicotine-containing products that is public health-based
- Understand implications for tobacco, drug, and device regulatory policy
  - Finalize Deeming regulation
  - Working with CDER and CDRH to determine how regulation of therapeutic nicotine products (Rx, OTC, drugs, devices) could evolve
  - Exploring options for expedited premarket review policy based on relative toxicity and risk
- Published Jurisdictional Proposed Rule
  - Describes circumstances in which a product made or derived from tobacco that is intended for human consumption will be subject to regulation as a drug, device, or a combination product under the FD&C Act

# Informing comprehensive nicotine policy – NCTR\*

**E07537.01** - Aspects of Nicotine Self-Administration in the Nonhuman Primate (Goodwin, A; Jackson, K)

**E07537.11** - Nicotine Nonhuman Primate Pharmacokinetic Study (Goodwin, A; Jackson, K)



# SETTING PRE- & POST-MARKETING POLICY

New rules and guidances issued in August and September 2015:

- Substantial Equivalence (SE) FAQ Final Guidance
  - FDA's current thinking on changes to tobacco products' label, product quantity in the package, additives, or specifications
- Nicotine Exposure Warning & Child-Resistant Packaging for E-Liquids ANPRM
  - Seeking information related to nicotine exposure warnings and child-resistant packaging for liquid nicotine, nicotine-containing e-liquid(s)
- National Environmental Policy Act (NEPA) Categorical Exclusions Final Rule
  - Adds exclusions to certain types of actions that do not normally cause significant environmental effects
- Investigational Tobacco Products (ITP) Draft Guidance
  - FDA's current thinking on definition of ITPs and kind of information FDA intends to consider when making enforcement decisions



## PRE- & POST-MARKETING REVIEW – NCTR\*

**E07447.11** - Use of New Technologies to Develop Biomarkers of Harm for New Tobacco Products (Yang, X; Yang, M)

**E07472.11** - Evaluation of Product and Physiologic Variables Influencing Smokeless Tobacco Toxicity (Chen, H; Yang, M)

**E07535.01** - CTP Scientific Enclave, TCKB, and Topic Modeling for Tobacco Industry Documents (Perkins, R; Aaronson, W; Sholtes, D)

**E07559.01** - CTP Bioinformatics Tobacco Constituents Knowledge Base and HPHC Toxicology (Perkins, R; Aaronson, W; Sholtes, D)



# FUTURE DIRECTIONS

## Research concepts under development with NCTR

- In Vitro-In Vivo Extrapolation of the Mutagenic Potential of NNK (Heflich, R and Yucesoy, B)
- Extrapolation of In Vitro Acrolein Dose-Response Derived in Air-Liquid Interface Airway Epithelial Models to In Vivo Lung Toxicity (Cao, X and Healy, S)
- Detection of NNK-Induced DNA Adduct Formation in Human Air-Liquid-Interface Airway Tissue Models (Pilot Study: Cao, X and Fu, X)

# DEFINING A PUBLIC HEALTH STANDARD

- Pursue a “public health” standard as tobacco cannot be regulated using FDA’s traditional “safe and effective” standard
- Take into account the benefits and the risks to both users and non-users of tobacco products
- Assess the “net” population-level health impacts of tobacco products



# REGULATORY SCIENCE DECISION MAKING

## Product Science

- Chemistry
- Engineering
- Microbiology

## Nonclinical Science

- Toxicology
- Pharmacology
- Biology
- Environmental Science

## Health Science

- Medicine
- Behavioral Pharmacology
- Psychology
- Neuroscience

## Population Science

- Epidemiology
- Social science
- Statistics, modeling
- Evaluation



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