

Update from the FDA Center for Tobacco Products

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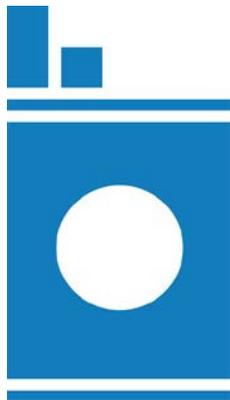
U.S. Food and Drug Administration

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Implementing the Tobacco Control Act



- Since 2009, CTP had authority to regulate tobacco products intended for human consumption to reduce harm across the population, including:
 - Reducing the number of people who start to use tobacco products
 - Encouraging more people to stop using these products
 - Reducing the adverse health impact for those who continue to use these products
- Regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own, and smokeless

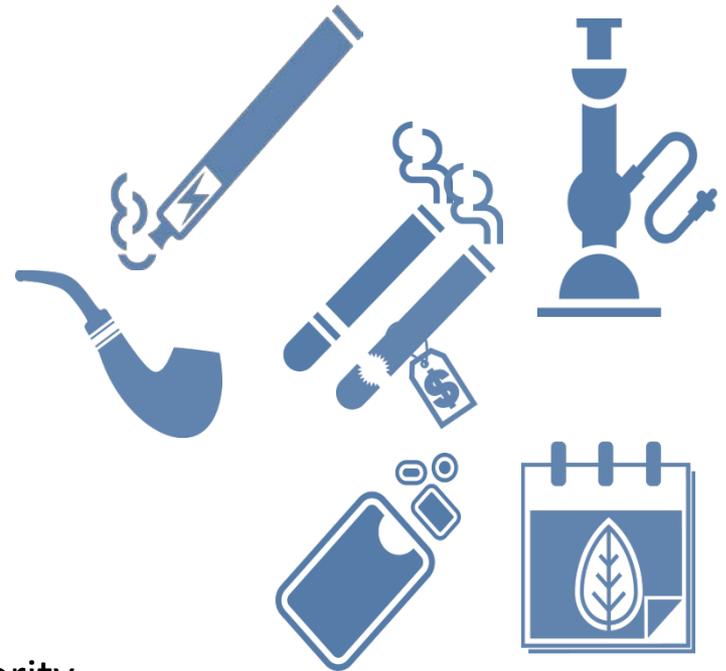


Tobacco Products Regulated



FDA finalized a rule effective August 8, 2016 to regulate all tobacco products meeting the statutory definition of a tobacco product , including components or parts (but excluding accessories), subject to FDA’s tobacco product authorities, including:

- Cigarettes
- Roll-Your-Own Tobacco
- Smokeless Tobacco
- ENDS (e-cigarettes, e-cigars, vape pens, etc.)
- All cigars
- Pipe tobacco
- Nicotine gels
- Waterpipe (hookah)
- Dissolvables not already under the FDA’s authority
- Future tobacco products



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



Addictive Nicotine in Combustible Cigarettes



“Nicotine is astonishingly addictive. And when nicotine is attached to cigarette smoke particles, it’s not only highly addictive, but an addictive chemical mix of disease and death.”

**FDA Commissioner Dr. Scott Gottlieb
July 28, 2017**

FDA's Comprehensive Regulatory Plan



FDA envisions a world where cigarettes would no longer create or sustain addiction, and where adults who still need or want nicotine could get it from alternative and less harmful sources

- Decrease the likelihood that future generations will become addicted to cigarettes
- Allow more addicted smokers to quit
- Encourage innovation of less harmful products for adults who need them
- Support innovations to medicinal nicotine and other therapeutic cessation products

FDA's Comprehensive Regulatory Plan



- New approach places *nicotine* – and the *issue of addiction* – at the center of regulatory efforts
- Acknowledging that while highly addictive, nicotine is delivered through products on a *continuum of risk* with the *most harmful* delivering nicotine through smoke particles from *cigarettes*
- Strikes an appropriate balance between *smart regulation* and encouraging *innovation of satisfying, less harmful* products
- Continue to base all actions on *regulatory* and *scientific foundation*



The Roadmap for a Healthier Future

- Publish product standards that reduce addictiveness, toxicity and/or appeal to prevent addiction, avert initiation, and encourage cessation among teens and adults
- Issue foundational rules to increase efficiency and transparency of product review process for industry
- Encourage innovative, less harmful, and satisfying nicotine products for adults who still need or want nicotine
- Address the role of all therapeutic products, including the performance of medicinal nicotine products, in order to help more smokers quit with help

Nicotine Product Standard ANPRM



- FDA will issue an Advance Notice of Proposed Rulemaking (ANPRM) to seek input on many topics including, but not limited to:
 - How manufacturers could comply with a nicotine product standard for cigarettes
 - Questions about potential unintended effects, such as compensation and illicit trade
 - Implementation and enforcement



Seeking Comment On Issues In Evolving Tobacco Marketplace



- Tobacco marketplace continues to evolve – and FDA is seeking additional information to inform other potential regulatory actions
- Future ANPRMs seeking comment on:
 - Role that flavors (including menthol) may play in 1) attracting youth and 2) helping some smokers switch to potentially less harmful forms of nicotine delivery
 - Scientific data on patterns of use and resulting public health impacts of premium cigars
- Potential product standards to reduce harms of non-combustible products
 - Reviewing comments on proposed product standard for N-nitrosornicotine (NNN) levels in smokeless products



CTP Research Program

- CTP funds research through collaboration with Federal agencies and contracts with non-HHS organizations that have particular expertise
- Priority Research Areas
 - Addiction
 - Chemistry and Engineering
 - Knowledge, Attitudes, and Behaviors
 - Toxicity and carcinogenicity
 - Health consequences
 - Communication
 - Marketing
 - Economics and policy

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





NCTR Projects Informing CTP*

- Evaluating the Toxicity and Inflammation Produced by Cigarette Smoke Using Human In Vitro Airway Models (Cao X, Healy S)
- 13-Week Nose-Only Inhalation Toxicity Study of NNK in Rats (Hu S, Chemerynski S, Yee S)
- In Vitro-In Vivo Extrapolation of the Mutagenic Potential of NNK (Heflich R, Yucesoy B)
- Self-Administration of Nicotine in Rats; Adolescent Exposure and in vivo Neuroimaging (Hiranita T, Hull L)
- High-throughput Screening Tobacco Constituents for Addiction Potential using Docking of Nicotinic Acetylcholine Receptors (Hong H, Leggett C)
- CTP Scientific Enclave, TCKB, and Topic Modeling for Tobacco Industry Documents (Perkins R, Aaronson W, Sholtes D)

**highlighted research examples-not exhaustive*

Research Areas of Interest

- Toxicity – Understanding how tobacco products and changes to tobacco product characteristics affect their potential to cause morbidity and mortality, including animal and cell culture models as well as novel alternative toxicology approaches that test the toxicity of tobacco smoke, aerosols, or specific constituents in tobacco
- Areas of interest include
 - Toxicological assays (in vivo and in vitro) to compare toxicity across different types of tobacco products within the same class including electronic nicotine delivery systems (ENDS), cigars, waterpipes and smokeless tobacco
 - How product design characteristics (and changes in those characteristics) impact constituent exposure and toxicity from tobacco products; biomarkers to assess exposure, as well as biomarkers to assess harm or toxicity of non-cigarette tobacco products, including ENDS

Research Areas of Interest

- Addiction – Understanding the effect of tobacco product characteristics on addiction and abuse liability
- Areas of interest include
 - Impact of changes in tobacco product characteristics (such as flavors or product design) on dependence
 - Differences in dependence and tobacco use patterns with use of low-nicotine-content cigarettes in context with other tobacco products
 - The amounts of nicotine delivered to ENDS users during experimentation, regular ENDS use, dual use of ENDS and cigarettes, and cigarette smoking quit attempts
 - Correlation of ENDS use behaviors with pharmacokinetic and pharmacodynamics effects of nicotine and other HPHCs delivered by ENDS

Thank You



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NCTR

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