



SMOKELESS TOBACCO AT THE FDA

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FDA Regulatory Authority Over Tobacco Products

- 2009 Family Smoking Prevention and Tobacco Control Act: FDA authority over cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco.
- FDA may “deem” other “tobacco products” subject to its authority, such as cigars and e-cigarettes.



Family Smoking Prevention and Tobacco Control Act Product Standards to Save Lives

- Family Smoking Prevention and Tobacco Control Act: FDA Authority to Force Industry to Make Products Less Lethal, Addictive and Appealing
- Possibilities:
 - Reduce nicotine level to reduce addictiveness
 - Prohibit flavorings to reduce appeal
 - Reduce levels of toxic substances



The Public Health Standard

- Section 907 of TCA: Grants FDA authority to issue product standards if “appropriate for the protection of the public health.”
- Requires determination of risks vs. benefits of proposed standard “to the population as a whole, including users and nonusers of tobacco products.”
- Effect on likelihood existing users of tobacco products will continue use, instead of quitting?
- Effect on likelihood that non-users will start using tobacco products?



Who Can Pronounce This?

- N-nitrosornicotine

First Tobacco Product Standard Proposed by FDA: Limiting NNN In Smokeless Tobacco

- Proposed rule limiting NNN in smokeless tobacco
 - Link between smokeless tobacco and oral cancer
 - NNN in smokeless tobacco drives excess cancer risk
 - Low NNN in Swedish snus supports feasibility
 - Higher NNN levels in other smokeless products
 - FDA estimates implementation of rule would prevent 12,700 new cases of oral cancer and 2,200 oral cancer deaths over next 20 years.





FDA's "New and Comprehensive Approach" to Nicotine Regulation

- Reduce nicotine in cigarettes to minimally addictive or non-addictive levels
- Need for innovation to develop less harmful nicotine products to cause smokers to switch – delayed regulatory compliance for e-cigarettes
- Develop more effective therapeutic products





Modified Risk Products

- What are they? Products marketed with claim they pose less risk than other tobacco products.
- Must meet rigorous public health standard
 - As actually used by consumers, will substantially reduce individual risk and benefit population as whole, including both users and non-users of tobacco products.



Smokeless Warnings Sought by Swedish Match Modified Risk Application

- ~~WARNING: This product can cause mouth cancer.~~
- ~~WARNING: This product can cause gum disease and tooth loss.~~
- ~~WARNING: This product is not a safe alternative to cigarettes.~~
- WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes.
- WARNING: Smokeless tobacco is addictive.



Camel Snus Modified Risk Application

v2

CAMEL

**NO SMOKE
LESS
RISK
CHOOSE
SNUS**



SNUS

WARNING: This product can cause mouth cancer.

CAMEL

WHAT IS CAMEL SNUS?

- Camel SNUS (rhymes with "moose") is finely ground premium tobacco in a soft fleece pouch.
- Like all tobacco products, Camel SNUS contains nicotine and is addictive.

HOW IS IT DIFFERENT?

- Many smokeless tobacco products, like dip and chew, are fermented loose tobacco.
- Sure, they're smoke-free, but they can get messy and require spitting.
- Snus is different. It's smoke-free, mess-free and spit-free.
- Camel SNUS is heat-treated, not fermented, and crafted with four main ingredients: tobacco, water, salt and flavoring.

HOW DO I USE IT?

- Slide a pouch under your upper lip.
- Taste the real, premium tobacco.
- Dispose of the pouch in the trash when you are finished.
- **Switch completely** from cigarettes to Camel SNUS.

4 SIMPLE MAIN INGREDIENTS

Tobacco + Water + Salt + Flavoring

Regular Large

2 POUCH SIZES
(actual size)

5 FLAVORS

15 POUCHES PER TIN

CUSTOMIZE YOUR ENJOYMENT WITH UP TO **30 MINUTES** OF FLAVOR PER POUCH

NO SMOKE = LESS RISK

Smokers who **SWITCH COMPLETELY** from cigarettes to Camel SNUS can greatly reduce their risk of lung cancer, oral cancer, respiratory disease and heart disease.

Scientific studies have shown that Camel SNUS contains less of the harmful chemicals than cigarette smoke.

Camel SNUS is smoke-free, so there are no secondhand smoke risks for those around you.

I'M A SMOKER. WHY SHOULD I SWITCH?

- Switching to SNUS means...
- Less of the harmful chemicals found in cigarette smoke
 - Less risk for you and those around you
 - No lingering smoke smell
 - Hassle-free tobacco



NO TOBACCO PRODUCT IS SAFE

- Like all tobacco products, Camel SNUS contains nicotine and is addictive.
- Adults who do not use or have quit using tobacco products should not start.
- Minors and pregnant women should never use tobacco products.
- If you're a smoker concerned about the health risks from smoking, the best choice is to quit. A good place to begin is talking with a healthcare provider.
- But if you're not going to quit using tobacco products, you should think about switching to Camel SNUS.

SNUS

WARNING: This product can cause mouth cancer.

SNUS

WARNING: This product can cause mouth cancer.

*WEBSITE RESTRICTED TO AGE 21+ TOBACCO CONSUMERS



Copenhagen Moist Snuff Modified Risk Application

- “IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer.”



How Can Your Voice Be Heard at FDA?

- FDA solicits public comments on proposed product standards and modified risk applications.
- FDA regulation not a spectator sport. Please file comments on with FDA on tobacco-related issues. You know the industry will!
- Can file electronically at [fda.gov/tobacco products](https://www.fda.gov/tobacco-products)

Navigate the Tobacco Products Section

[Products, Guidance & Regulations](#) 

FDA's approach to regulating tobacco products is grounded in science and uses the full power of the law to protect public health.



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