Harm Reduction

Food & Drug Administration

Modified Risk Tobacco Products

April 15, 2013

Tobacco Control Legal Consortium

The Tobacco Control Legal Consortium

A national legal network supporting tobacco control policy change.

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North Dakota Harm Reduction Language

Original language

"That . . . Legislative Management study opportunities to reduce the risk of death and disease among smokers who will not quit smoking, by considering tobacco harm reduction strategies that encourage smokers to switch from cigarettes to less-risky tobacco products and by accurately informing the public of the health risks posed by smokelss tobacco products, vapor products, and tobacco-derived products relative to cigarettes…"

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North Dakota Harm Reduction Language

Amendment language

"Legislative Management shall consider studying, during the 2013-14 interim, opportunities to reduce the risk of death and disease through harm reduction strategies. The legislative management shall report its findings and recommendations, together with any legislation to implement the recommendations, to the sixty-fourth legislative assembly."

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FDA Modified Risk Tobacco Products Review Process

- **Modified risk products:**
  - **Significantly reduce harm and risk of tobacco-related disease to individual tobacco users**
  - **Benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products**
- **Numerous requirements for evidence and marketing**

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FDA Modified Risk Tobacco Products Review Process

- **Special Rules for Certain Products (expedited):**
  - **Would be appropriate to promote the public health**
  - **Limits marketing information**
  - **Scientific evidence is not available and involve long-term studies**
  - **Any scientific evidence that is available demonstrates reduction in harm**

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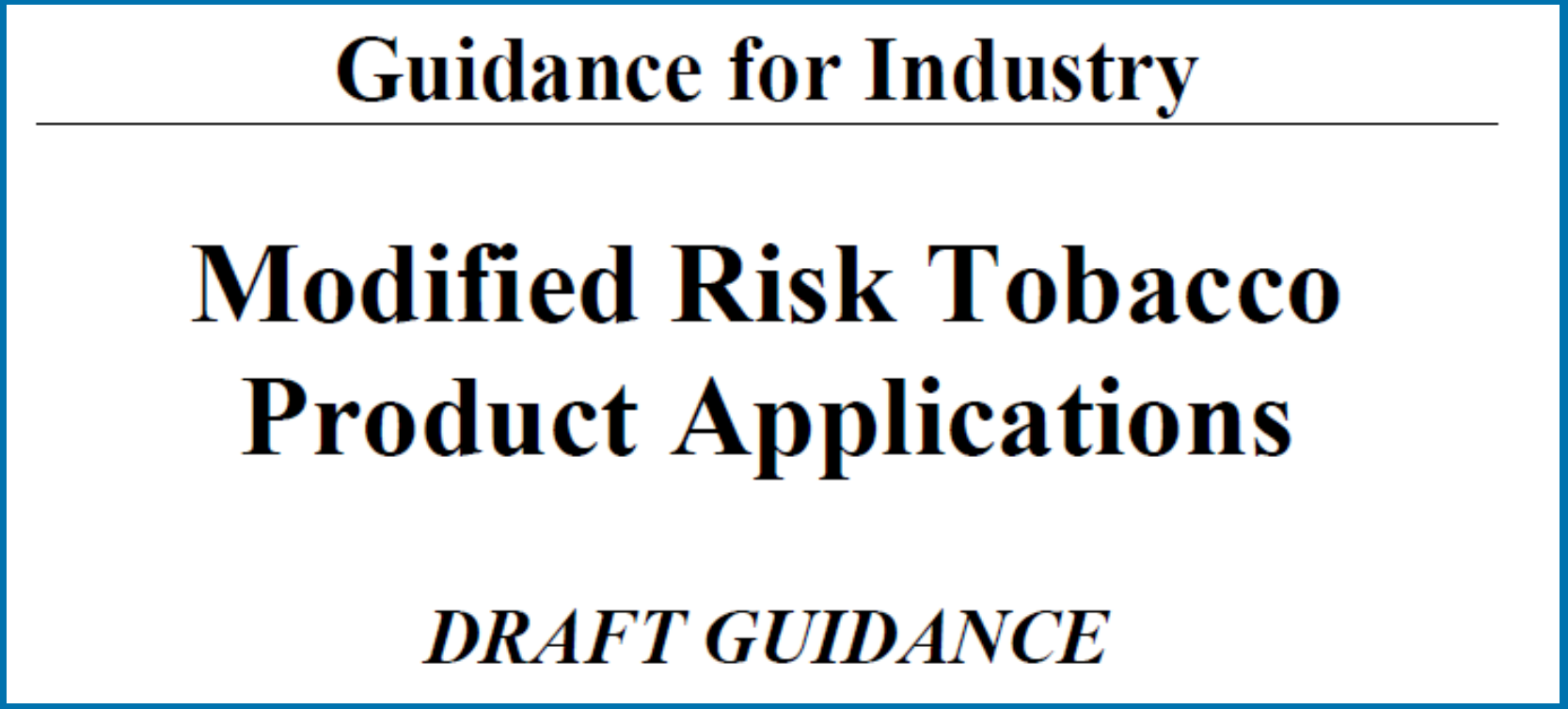
FDA MRTP Process
Draft Guidance



http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm297750.htm

Issues / Talking Points:

- FDA review process is in place
- Industry prohibited from making modified risk claims prior to FDA review
- Are potential “harm reduction” products, such as e-cigarettes, subject to FDA regulation?
  - FDA authority extends to cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco
  - “Deeming” regulation may be announced in April?

Issues / Talking Points:

- Why would states incur the research and study costs?
  - FDA already has process
- What would states do with study reports?
  - States are preempted from issuing tobacco product standards
  - Danger of states preempting local government action on alleged harm reduction products

Contacts

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