



Dissolvable Tobacco Products

Tobacco Products Scientific Advisory Committee Meeting
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DISCLAIMER: The information in these materials is not a formal dissemination of information by FDA and does not represent agency position or policy. The information is being provided to TPSAC to aid the committee in its evaluation of the issues and questions referred to the committee.

Charge to the Committee*

- The Tobacco Products Scientific Advisory Committee (TPSAC) is required to review and provide recommendations to FDA regarding the “the nature and the impact of the use of dissolvable tobacco products on the public health, including such use among children.”

*Section 907(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Charge to the Committee*

- TPSAC is to consider:
 - The risks and benefits to the population as a whole, including users and non-users of tobacco products, of the proposed standard;
 - The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
 - The increased or decreased likelihood that those who do not use tobacco products will start using such products.
- TPSAC report and recommendations are due March 23, 2012.

*Sections 907(a)(3)(B) and 907(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Tobacco Product

- “any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).” FD&C Act § 201(rr)(1).
- “does not mean a product that is a drug, a device, or a drug-device combination product.” FD&C Act § 201(rr)(2).

Regulated Tobacco Products

- Currently, cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco are subject to regulation under Chapter IX. FD&C Act § 901(b).
- FDA intends to propose a regulation that would deem products meeting the statutory definition of “tobacco product” found at section 201(rr) of the FD&C Act to be subject to FDA’s jurisdiction. FD&C Act § 901(b).

Smokeless Tobacco

- “any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity” (FD&C Act § 900(18)).

Dissolvable Tobacco Products

- There is no statutory definition of “dissolvable tobacco product.”
- We believe that many dissolvable tobacco products meet the current statutory definition of “smokeless tobacco.”
- It is possible that some dissolvable tobacco products are not currently regulated under Chapter IX of the Tobacco Control Act.

Meeting Topics

- The topic is specifically dissolvable tobacco products, not smokeless tobacco in general.
- TPSAC is **not** being asked:
 - to address use of dissolvable tobacco products as cessation aids (e.g. as a drug);
 - whether specific products are substantially equivalent to products which were on the market on February 15, 2007;
 - at this time, to evaluate individual applications;
 - to address use of dissolvable tobacco products as potential modified risk tobacco products.*

*FDA has planned a public workshop on this issue in August. The Institute of Medicine is also currently considering this issue.

Meeting Topics Continued

- In reviewing “the nature and the impact of the use of dissolvable tobacco products on the public health...,” FDA requests that TPSAC be inclusive, e.g.:
 - Without regard to whether they are currently regulated (i.e., not limited to products that meet the definition of “smokeless tobacco.”)
- In providing recommendations to FDA, we request that TPSAC identify the types of dissolvable tobacco products to which the advice does and does not apply.



Industry Presentations

Industry Presentations

Manufacturers which FDA had reason to believe were marketing dissolvable tobacco products as of June 2011 were invited to present at today's TPSAC meeting. These presentations are voluntary and intended to give Industry an opportunity to inform TPSAC.

Response to Industry Invitations

Today's session:

- Altria Client Services – declined
 - RJ Reynolds – accepted
 - Star Scientific, Inc. – accepted
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- If other manufacturers who make a dissolvable tobacco product are identified, they may be invited to speak at future TPSAC meetings.

Focus of Industry Presentations

FDA requested Industry presentations to TPSAC be **organized by topic**, not by company:

1. Marketing and Consumer Perception
2. Abuse Liability and Health Risks
3. Initiation and Cessation

FDA requested that each company present Industry data and peer reviewed literature relevant to each of the three topics.

FDA asked each company to submit a background package to the committee with more detailed information on these same topics.

Topic 1:

Marketing and Consumer Perception

- Description of dissolvable tobacco product(s) that your company has marketed or plans to market;
- Marketing and segmentation strategies for dissolvable tobacco products;
- Description of how the products are designed, manufactured, and marketed to reach your target market;
- Perception and use of dissolvable tobacco products by children and adolescents, and, even in the absence of test data, any properties which might make these products more or less attractive to children and youth.

Topic 2:

Abuse Liability and Health Risks

- Abuse liability of dissolvable tobacco products including: product design, quantity and form of nicotine, pharmacokinetics of nicotine, potential impact on non-targeted populations. Also discuss efforts to limit or reduce abuse liability;
- Discuss the safety profile of dissolvable tobacco products, including available information on both local and systemic adverse health effects specific to dissolvable products;
- Risks associated with accidental ingestion of dissolvable tobacco products by children.

Topic 3:

Initiation and Cessation

- Whether dissolvable tobacco products might be used as starter products for non-users and how composition and design features impact use by non-tobacco product users;
- Likelihood that users of tobacco products will completely switch to dissolvable tobacco products, as opposed to a pattern of dual use;
- Likelihood of dissolvable tobacco products users quitting tobacco consumption in comparison to users of other tobacco products.



Clarifying Questions?