
Some devils that may be lurking under the details of FDA tobacco regulations

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Outline

- Background
- Objective
- The details of the devils
- Conclusions

Background

- Much has been said about proposed FDA regulations, especially about marketing regulations and testing requirements
- However, the problems for the industry, especially the smaller companies, may be in the very minor details
- Normal manufacturing issues that previously may have been overlooked or considered to be only consumer annoyances, may be the issues that need more attention

Objectives for presentation

- Alert interested parties to potential problems
- Determine if there is consensus that potential problems have been correctly identified
- Help achieve consensus on potential solutions to potential problems

Example 1 - Defects in finished product

- Consumer annoyances or adverse events reportable to FDA?
 - Cigarettes
 - Coal fallout or loosely packed tobacco rod
 - Loose or missing filter or wrong filter
 - Odd taste or wrong flavor (menthol in nonmenthol style)
 - Stale/dry (poor packaging, incorrect storage, wrong humectant level)
 - Infestation and other foreign matter
 - Smokeless products
 - Odd taste, wrong flavor, not enough flavor
 - Stale/dry (poor packaging, outdated product)
- If adverse events, will pharmaceutical-style investigation and reporting be required?

Example 2 - Ingredients

- FDA is likely to focus on ingredients
 - Those alleged to increase product desirability
 - Those alleged to aid nicotine manipulation
 - Those alleged to be unsafe or unsafe for use in cigarettes and other smoking products
- Studies have shown safety of commonly used ingredients, but skepticism remains
 - Equivalence of ingredients tested to those used (e.g., differences in sugars, cocoas, etc)
 - Purity of ingredients and traceability
 - Points of addition and conditions of use in processes and/or products (e.g., sugars as humectants versus use in cooked reaction flavors)

Example 3 - Manufacturing issues

- cGMP for tobacco products
 - Tobacco Products Safety Advisory Committee (TPSAC) helping set the rules
 - Delay for small manufacturers for some cGMP and testing requirements, but not other rules
- Adulteration and contamination
 - Common production issues may get magnified
 - Infestation and other foreign matter
 - Mold, other contamination (including wrong additives)
 - Improper cleaning and lubrication of equipment
 - Will entire batches of tobacco be declared unfit or will use of unaffected portions be permitted?
 - How will transfer of packaging chemicals to products be treated?

Conclusions

- The devils will definitely be in the details of the regulations and their enforcement
- The small manufacturer exemption from cGMP may do more harm than good
 - Adherence to cGMP would likely decrease chances of adverse events affecting consumers
 - Adherence to cGMP would likely decrease chance of manufacturing-related adulteration and contamination issues
 - Costs of identifying causes of adverse events and manufacturing issues can be very high so common approach will be needed