

Mislabeling, Misbranding, and Product Adulteration

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Outline for presentation

- Background
- Objective for presentations
- Examples of misbranding and adulteration
- Keeping out of harm's way
- Conclusions

Background

- Much has been said about FDA bill, especially about marketing restrictions, costs of compliance, and product testing
- However, the problems for the smaller companies may be in the more minor details
- Manufacturing issues that previously may have been overlooked or considered to be only consumer annoyances, may now be viewed as misbranding (mislabeling) or adulteration

Objectives for presentation

- Provide working definitions of misbranding (mislabeling) and adulteration
- Give some actual examples of misbranding and adulteration
- Provide practical ways to minimize chances of misbranding and adulteration occurring in your products (and maybe even save you some money while making better products)

Misbranding – adopted from Section 903

- A tobacco product shall be deemed to be misbranded if
 - Its labeling is false or misleading in any particular
 - If in package form unless it bears label containing
 - The name and place of business of the tobacco product manufacturer, packer, or distributor
 - An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count
 - An accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco

Adulteration – adopted from Section 902

- A tobacco product shall be deemed to be adulterated if
 - It consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health
 - It has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health
 - Its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health

Adulteration – adopted from Section 902 (continued)

- A tobacco product shall be deemed to be adulterated if
 - It is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under § 907 unless such tobacco product is in all respects in conformity with such standard
 - Section 907 deals with tobacco product standards (certain flavors, agrochemical residues, product design, testing, etc.)
 - The methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under § 906(e)(1) or an applicable condition prescribed by an order under § 906(e)(2)
 - Good manufacturing practice (GMP) requirements [§ 906(e)(1)] or exemption from GMP [§ 906(e)(2)]

Adulteration – adopted from Section 902 (concluded)

- A tobacco product shall be deemed to be adulterated if
 - It is required by § 910(a) to have premarket review and does not have an order in effect under § 910(c)(1)(A)(i)
 - You don't have order under § 910(c)(1)(A)(i) permitting your product
 - It is in violation of an order under § 910(c)(1)(A)
 - You have an order under § 910(c)(1)(A) forbidding or restricting sale of your product
- It is in violation of section 911 (rules for modified risk products)

Examples of what FDA may consider to be misbranding

- Incorrect count or weight or wrong/poorly made recipe
- Incorrect characterizing flavor on noncigarette product
- Menthol in nonmenthol product
- No menthol or no apparent menthol attributes in menthol product
- Wrong brand/style in package
 - ❑ Package says Brand A, but tipping is for Brand B, or product is really Brand B
 - ❑ Package is for full-flavor brand, but product in package is really a low-delivery version of the brand
 - ❑ Your package contains someone else's brand/style

Examples of what FDA may consider to be adulteration - 1

- Active insect or rodent infestation or signs of past infestation (beetle holes in product)
- Use of moldy, spoiled, improperly processed tobaccos
- Foreign matter in the product
 - Foreign matter coming in with tobaccos/ingredients
 - Overly large pieces of stem, padded tobaccos, string, foam
 - Ingredients contaminated in loading, shipping, unloading
 - Foreign matter that comes from your factory
 - Cleaning and maintenance – broom bristles, nylon wire ties
 - Contamination from equipment – worn/broken belting, wrong coatings on process equipment, lubricants
 - Security-related issues

Examples of what FDA may consider to be adulteration - 2

- Use of processed tobaccos and ingredients that smell, look, feel, or taste bad or differently than expected or are suspected of being out-of-specification
- Contamination from packaging and nontobacco materials (e.g., cigarette paper, filter rods, adhesives)
 - Printed materials are frequently sources of contamination that could be viewed as adulteration
 - Soft-cup labels and hinged-lid boxes
 - Tipping papers
 - Packaging and nontobacco materials that are improperly stored or become contaminated in transportation

Keeping out of harm's way - 1

- “Our consumers inspect our products stick-by-stick,”
Tommy E. Sandefur
- We want happy consumers who buy our products day-after-day and have no reason to call the FDA
- Minimizing the chances of a misbranding or adulteration incident is not “rocket science”
 - ❑ It requires cooperation and teamwork among all stakeholders
 - ❑ It requires education of our employees and vendors
 - ❑ It is likely going to have some initial costs for baseline testing and “paperwork”
 - ❑ But, if done right, it should benefit all our stakeholders

Keeping out of harm's way - 2

- Make your requirements known to your vendors
 - Get meaningful specifications from your vendors
 - Additives used on your tobaccos and in burned portions of any products should have food status (e.g., food chemicals codex)
 - Packaging materials should be approved for food use
 - Vendors should certify absence of CA Proposition 65 compounds
 - Get certificates of analysis for everything you buy, including tobaccos
 - Visit vendor's facilities and see how your materials are processed, packed, stored and shipped
- Educate your employees on how good tobaccos and ingredients should look and smell and reward your employees for pointing out potentials problems

Keeping out of harm's way - 3

- Keep your facilities secure to prevent situations that might lead to adulterated or misbranded products
- Make sure your quality checks on in-process materials and outgoing products are appropriate
 - ❑ Do you have a statistically-based sampling plan?
 - ❑ Do your finished products look and smell like they should?
 - ❑ Are you making enough measurements (weight, moisture, other physical tests as appropriate) to show that your products would likely give the correct nicotine deliveries if tested?
 - ❑ Are you keeping retained samples of each batch?
- Do your employees know what to do when a consumer contacts your company with a product-related concern?

Conclusions

- Minimizing occurrences of misbranding and adulteration of your products requires teamwork among all stakeholders and a common-sense approach to potential issues
- You cannot test everything or be on the factory floor all the time – your employees must know good from bad and be rewarded for bringing potential problems to management's attention
- You need to welcome consumer comments as they may be the first warning that you have potentially bad product on the market