

Swedish Match U.S. Sales National Meeting

FDA Overview & POS Transition Plan



Scottsdale, AZ February 4, 2010

FDA Overview

Please note that certain components of the FDA Bill have been challenged in court and are now in the Appeals process:

- On January 5, 2010 a Federal Judge ruled that a ban on the use of "color" advertising is unconstitutional:
 - This includes the use of logo's and imagery
 - > Directly impacts POS and promotional Displays which are considered Advertising

We don't expect the appeals process to conclude before June 22nd. Updates to the following presentation and implementation plan will be communicated when they become available

FDA Overview - Why, What, When?

- Regulate the manufacture and processing of tobacco from the grower to store shelves
 - Good Manufacturing Practices (GMP's)
 - Facility Registrations, Product Listings, Inspections
- Subject new product to pre-market oversight
 - > Testing
 - ➤ Modified risk claims (light, mild, etc...)
- Transparency regarding ingredients and risk
 - Disclosure of ingredients
- Additional restrictions on tobacco advertising and promotion
 - Particularly as directed to minors
- Foster the development of less harmful tobacco products and smoking cessation products

FDA Overview— Why, What, When (cont'd)

 Law applies only to cigarettes, cigarette tobacco, Roll-Your-Own, and smokeless tobacco (Does not include Cigars or Pipe Tobacco!)



- Focus of this discussion is related to FDA impact on Smokeless Tobacco
- Other tobacco products such as Cigars can be brought into the scope of the act in the future
- Does not preclude regulation of tobacco by other federal (Health and Human Services) or local agencies (i.e. State and local laws can be even more restrictive than federal laws)

FDA Overview – Why, What, When (cont'd)

- Key Dates
 - June 22, 2009 FDA Bill signed into law
 - January 5, 2010 Federal Judge rules that limiting the use of "color" advertising is unconstitutional
 - March 2010 Final Rule due from FDA
 - June 22, 2010 FDA Regulation goes into effect
 - Applies to all aspects of Packaging, Advertising, and Promotion
 - Absolute last day for <u>manufacturers</u> to ship non-FDA compliant packaging is July 22nd (includes 30 Day "grace" period on packaging requirements)

FDA – Advertising

- No advertising on television or radio
- Advertising is <u>permitted</u> in newspapers, magazines, brand web-sites, billboards, posters, point-of-sale (including audio & video) as long as it complies with the following restrictions:
 - Warnings must appear on advertising and <u>cover at least</u>
 20% of advertising space
 - Audio advertising limited to words only with <u>no music or sound</u> effects
 - Video advertising limited to <u>static images</u> (e.g. Brand websites)
- Direct mail permitted as long as it is directed to consumers of legal age

FDA – Consumer Promotions

- No sponsorship of events or teams
- Sweepstakes permitted, as long as compliant with federal law:
 - Not advertised on product label
 - Not conditioned on product sale
 - No branded non-tobacco products as prize
- Coupons permitted if offered as price reduction on current purchase (i.e. cents off, buy one get one free)
 - cannot be tied to any non-tobacco product purchase or future tobacco purchase (i.e. Free Gas, Catalina, etc...)
 - No free can coupons permitted
- No branded non-tobacco products permitted
 - May no longer distribute branded merchandise (e.g. clothing, clocks, etc...)
 - May no longer offer gifts or other items in consideration for buying cigarettes or smokeless tobacco (e.g. TW Get the Gear, Camel Cash, etc...)

FDA – New Packaging Label Requirements

- New label requirements include:
 - Name and place of manufacturer
 - Statement of quantity (weight or measure)
 - Statement of identity (Loose Leaf, Moist Snuff, SNUS, etc...)
 - % of Domestic and/or foreign tobacco
 - Origin statement (sale only allowed in the United States)
 - Black & White Warning Statement minimum <u>30%</u> of two primary display panels (under customary conditions for retail sale)
 - Brand, Flavor, Cut
 - Date Code (no change from current process)
 - UPC

Important Note:

New packaging must begin shipping from manufacturers warehouses by June 22nd (plus 30 day "grace" period if needed). Pre-FDA packaging already at wholesalers and retailers is good for normal wholesale and retail flow through. THIS PRODUCT SHOULD NOT BE RETURNED!

FDA – New Packaging Label Requirements (cont'd)

Examples of "new" FDA Compliant Packaging







Warning Statements = 30% of Two Primary Display Panels

FDA – Trade Promotions

Limitations

- Effective June 22nd the following limitations apply to <u>all</u> retail outlets including Convenience, DTO's, Food, Drug, Mass, and Club, that do not qualify as a "Qualified Adult Only Facility" (QAOF):
 - All Promotional Displays must conform to new <u>Advertising</u> regulations (20% of space on primary display panels dedicated to mandated "health warnings") This includes Chew Floor Displays, MS Towers, and MS Dump Bin's
 - All product must be behind counter in a non-self serve environment
- If a facility (i.e. DTO) qualifies as a "QAOF", it can merchandise product in a self-serve environment
- To qualify as a "QAOF" it must adhere to the following rules:
 - Must be 18 or older to enter

FDA – Trade Promotions (cont'd)

In-Store Promotions/TPR's

- Post June 22nd, all SMUS Factory Promotions will conform to the new Advertising regulations:
 - 20% of space dedicated to mandated "health warnings"
 - Small enough to adhere to behind counter regulation (i.e. no floor displays except in DTO's that qualify as QAOF's)
 - Not tied to any sweepstakes or premium giveaways

- TPR's are permitted including "Buy X Get X promotions"
 - However, price reduction cannot be tied to any non-tobacco product or promotion (i.e. Free Gas) OR any future purchase of tobacco or non-tobacco products (i.e. Catalina Coupons)

FDA – Trade Promotions (cont'd)

1st Half SMUS Smokeless Displays/Promotions

		Permitted at Retail		
		after June 22 nd ?	<u>Notes</u>	
•	Wave 1 Longhorn Pre-Priced Displays	No	(1)	
•	Wave 1 TW Snipe Displays	No	(1)	
•	Wave 1 RMMS Pre-Price Displays	No	(1)	
•	Wave 1 LH, TW, RMMS Dump Bin Displays	No		
•	Wave 1 RMO, RMGB, SP Displays	No	(2)	
•	Wave 1 RMO, RMGB, SP Open Stock Promot	ion Yes	(3)	
•	Wave 1 RMSB Trial Size \$1.49 Display	No	(2)	
•	Wave 1 JD's Pre-Priced Displays	No	(2)	

Footnotes:

- (1) Snuff promotional towers are considered advertising. Since they will not carry the mandated 20% health warning, they must be removed from retail by June 22nd. However, the pre-FDA promoted cans are still permitted and should be relocated to the rack along with Open Stock
- (2) Chew displays are considered advertising. Since they will not carry the mandated 20% health warning, they must be removed from retail by June 22^{nd.} However, the pre-FDA <u>promoted cartons</u> and/or pouches are still permitted and should be relocated to the Open Stock area
- (3) Chew Open Stock Promotions are permitted because there is no display vehicle (no advertising)

FDA – Retail Merchandising & POS

- All tobacco products must be sold in <u>non self-serve environment with the exception of DTO's qualifying as QAOF's</u>
- POS can be used anywhere in store <u>including outside signage and</u> <u>signage facing outside of store (applies to all retail outlets)</u>
- Minimum of 20% of space must be designated to health warnings
- Price callouts and colored price bursts are <u>permitted</u>
- No size limit for exclusion of health warnings (<u>ALL</u> POS material must have health warnings regardless of how small the item is)
 - However, we will use discretion when the item is so small that the warning or the brand name would not be legible (i.e. shelf labels)

FDA – Retail Merchandising & POS (cont'd)

FDA Compliant POS & Merchandiser Examples

20% of Space allocated to Health Warnings*









FDA – Shared Responsibility

Shared responsibility between manufacturers and retailers for compliance

- Manufacturers responsible for removing from retail noncompliant items that they own
- Retailers are ultimately responsible for ensuring compliance, irrespective of ownership
- All parties must show "good faith" effort to be in compliance by June 22nd

Retailer Age Verification

- Retailers are expected to adopt a written policy regarding sales to minors, to inform all employees of the age verification requirements, to establish sanctions for employees who violate the requirements, and to require employees to verify age by checking ID's.
- FDA will develop a training program for retailers. Retailers who adopt a training program face lesser penalties than those who do not. Escalating scale for penalties will be enforced (6 or more in 36 months will be \$10,000 fine)

FDA – Sampling

- Sampling of smokeless tobacco allowed <u>only</u> in Qualified Adult Only Facilities (QAOF's) under the following regulations:
 - Restricted areas that require identification to officer or security guard licensed by governmental entity
 - No alcohol sold, served, or distributed
 - Cannot be adjacent to, or across from, spaces used for youth-oriented marketing, promotional, or other activities
 - Must be temporary structure operating for purpose of distributing free samples
 - Enclosed by barrier of certain size, material that prevents those outside from seeing inside
 - On outside, NO advertising or brand name other than in conjunction with words to identify the QAOF
 - One package (15 grams or .53oz) per person, per day, per manufacturer
 - No sampling at sporting events or to sports teams (except NASCAR events)
 - No consumer intercept, daily sampling, or local event sampling will be permitted by SMUS Sales Rep's...<u>NO EXCEPTIONS</u>!

FDA – Sampling (cont'd)



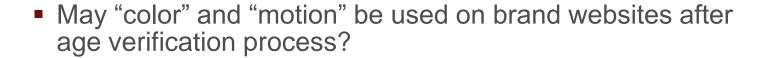
Example of FDA Compliant Sampling Trailer

FDA – Areas being challenged or awaiting Final Rule???





- Use of brand logo's (i.e. Indian Head in Red Man logo)
- Use of imagery (i.e. Longhorn Bull)
- Is a picture of the "can" or "pouch" considered imagery?
- If it is determined that the use of "color" POS is not allowed for retail outlets, can "color" be used in the outlets considered QAOF's?
 - DTO's?







FDA – Key Date Review

- "Final Rule" expected in late March 2010
- Labeling requirements for smokeless tobacco products effective June 22nd
- 30 day grace period on manufacturer labeling requirements (<u>open stock product</u> with pre-FDA labeling is okay at retail as long as it shipped from manufacturer by July 22, 2010...No Returns from Retail or Wholesale!)
- Advertising requirements become effective June 22, 2010 (includes POS material, removal of Wave 1 Moist Snuff Towers, and any MS/Chew Floor Displays)
- All non-compliant pre-FDA POS (color) must be out of retail by June 22nd!