

Consumer Satisfaction and FDA Regulation

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Outline for presentation

- Background
- Objective for presentations
- Importance of maintaining consumer satisfaction
- Ingredient disclosure – why it is different this time
- Conclusions

Background

- We have had over seven months of FDA regulation
 - Creation of Center for Tobacco Products (CTP)
 - Initial flurry of activity– ban of certain flavored cigarettes
 - Other actions on product-related issues
 - Postponement of deadlines (ingredient reporting, nicotine reporting in cigarette tobaccos)
 - Final Guidance for Industry: Listing of Ingredients in Tobacco Products (FDA ignored comments on bad science)
 - Letters to Star Scientific, RJRT on dissolvable smokeless tobacco products sent on February 1
- Little affect on STPM, but not time to be complacent
- Get ahead of the curve while there is still time to ensure that your products will stay in compliance

Objectives for presentation

- Explain why maintaining consumer satisfaction is congruent with complying with current and expected FDA actions and regulations
- Explain why FDA ingredient reporting should not be left to the last minute
 - Differences with ingredient reporting to other entities
 - Complexities of obtaining information and preparing data for submission by June 22 deadline
- Explain why doing a good job on ingredient reporting now can lead to increased consumer satisfaction

Importance of maintaining consumer satisfaction

- “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
- Do you want your consumers to contact you if they have a concern or do you want them to send e-mail to:
AskCTP@fda.hhs.gov (address for general consumer inquiries at FDA/CTP)?
- There is little likelihood of good things happening to you if your consumers contact the CTP

Making consistent quality products

- Having GMP should be a future objective, but it
 - Does not replace common sense manufacturing practices
 - If it looks, smells, or feels bad, don't let it in your plant
 - If you think it is bad, don't use it – you can't blend-off contamination
 - If it doesn't look right, smell right, or smoke right, don't ship it
 - Does not replace keeping factory clean, infestation-free, and equipment in good repair
 - Belting, broom bristles, insects, and moldy tobacco do not smoke well
 - Foreign matter in STP can be a serious issue
 - Does not replace listening to consumers and your employees
 - Calls from consumers should be welcomed and rewarded, they are better than those from the FDA
 - Train and reward employees for alerting you to problems, both real and potential, in your processes and products

Keeping consumers happy

- Part of tobacco GMP may be adverse event reporting
 - Adverse events could include product that has manufacturing defects and/or poor hedonic properties
 - Defective product may also be considered misbranded and/or adulterated and rules forbidding misbranded and/or adulterated products are already in effect
 - Calls from consumers may be the first clue that you have a problem in the marketplace
 - Reward consumers for calling you
 - Act promptly on the information they give you
 - Use consumer feedback to improve your products
 - It is always cheaper to minimize chances for defective product to get out than it is to recall it from the marketplace

Timing and complexities of ingredient reporting

- Ingredient reports now due June 22, 2010
- FDA reportedly will limit focus to certain categories
 - Manufacturers and importers of cigarettes, smokeless tobacco, and roll-your-own tobacco for consumer use
 - Manufacturers and importers of tobacco (including tobacco leaf blends, reconstituted tobacco, and bulk smokeless tobacco), papers, filters (including filter rods), or pouches, whether such products are for further manufacturing of, or for consumer use as, regulated tobacco products. Products for consumer use include tobacco, papers, and filters sold separately, in kits (such as for roll-your-own tobacco), or as part of accessories.

Differences with prior reporting requirements

- Differences among FDA reporting and reporting to DHHS under FCLAA (cigarettes) and CSTHEA (STP)
 - FCLAA and CSTHEA
 - Focused only on finished products sold to consumers
 - *Qualitative* listing of ingredients added to tobacco [just ingredient name and Chemical Abstracts Service (CAS) registry number]
 - No need to list ingredients in nontobacco materials (e.g., cigarette paper, filter) and packaging
 - No need to list compounds formed when ingredients react with each other or with tobacco constituents
 - No testing required except for nicotine, moisture, and pH as specified in CSTHEA
 - FDA rules unlike FCLAA and CSTHEA require *quantitative* data (e.g., amount of ingredient per cigarette)

Example FCLAA report form for cigarettes

Recommended Ingredient Reporting Format - FCLAA
Please attach additional pages if necessary

Date 2/3/2010

Office on Smoking and Health
Attn. FCLAA Program Manager
4770 Buford Hwy., NE, MS K-50
Atlanta, GA 30341

This ingredient report is being submitted pursuant to the Federal Cigarette Labeling and Advertising Act (FCLAA), 15 U.S.C. Section 1335a.

Company Name(s)* Lauterbach & Associates LLC

Brand(s)† John's Special Blend

Product type(s)† (check all that apply)

- cigarettes
 bidis
 kreteks
 other _____ (specify)

*If this Ingredient Report is submitted by a designated individual or entity on behalf of a cigarette manufacturer, packager, or importer, the form must specify on whose behalf the submission is being made.

†Inclusion of the brand name and product type is not required under FCLAA.

<u>Ingredient Name</u> ¶	<u>CAS Registry Number</u> §
Glycerin	56-81-5
High fructose corn syrup	9770-42-844

¶ Pursuant to FCLAA, 15 U.S.C. Section 1335a(2)(A), ingredients will be kept by OSH as trade secret or confidential information subject to section 552(b)(4) of Title 5 and section 1905 of Title 18. Also include each of the ingredients that constitute the flavors that are added to the products.

§ Chemical Abstract Service Registry Number, available from the National Institutes of Health National Library of Medicine at <http://chem.sjs.nlm.nih.gov/chemidplus/chemidheavy.jsp> or from the Food and Drug Administration at <http://www.fda.gov/cder/ig/igfaqWEB.htm>.

Information needed to do FDA report on John's Special Blend

- Blend formula and curing method for each leaf type
- Average tobacco weight per cigarette and identity and amount of each tobacco additive per cigarette
- Average weight of paper type used per cigarette and identity and amount of each paper additive per cigarette
 - Cigarette paper
 - Tipping paper
 - Filter plug wrap
- Average weight of filter tow and identity and amount of each filter additives used
- Average dry weight and identity of each adhesive used to fabricate product

Other information needed for FDA report on John's Special Blend

- Compositions of foil innerwrap, label or FOB, packaging film, tear tape, and each adhesive used to estimate amounts and identities of packaging volatiles that will transfer to the product
- Knowledge of how tobacco was processed is needed to estimate reaction products that will be formed
 - Is all HFCS applied to burley tobacco and redried?
 - Is all HFCS applied across total blend and not redried?
 - How was cut tobacco dried?
 - How was reconstituted tobacco prepared?
- Getting information and writing the report takes time and expertise; do not delay

Example of part of FDA ingredient reporting form

SECTION IV - INGREDIENT LISTING	
<i>Use a separate copy of Section IV for each ingredient you list or update.</i>	
Product Name*	Ingredient Name
John's Special Blend (KS)	High fructose corn syrup
FDA-Assigned Tracking Number	Ingredient Number (IN#)
	2
1. If this is an update to report a change in an additive, identify type of update and the date that the change was made.	
1a. <input type="checkbox"/> Quantity of additive was increased* Date of change (mm/dd/yyyy): _____	
1b. <input type="checkbox"/> Quantity of additive was decreased* Date of change (mm/dd/yyyy): _____	
1c. <input type="checkbox"/> Additive was eliminated* Date of change (mm/dd/yyyy): _____	
1d. <input type="checkbox"/> Additive was added* Date of change (mm/dd/yyyy): _____	
PART 1: INGREDIENT IDENTIFICATION (Complete only A, B, or C, as appropriate)	
A. Single Chemical Substance	
1. Unique Scientific Name or Code*	
977042844	
2. Type of Code <input type="checkbox"/> FDA UNII Code <input checked="" type="checkbox"/> CAS Number	
<input type="checkbox"/> IUPAC Name <input type="checkbox"/> Other (Specify): 0	
3. Is this ingredient a Reaction Product? <input type="checkbox"/> Yes (See immediately below) <input checked="" type="checkbox"/> No (Skip to Part 2)	
If Yes, FDA requests that you list the IN# of all ingredients known or intended to form this product.	
IN#	IN#
IN#	IN#
B. Leaf Tobacco	
1. Type (e.g., Burley, Bright, Oriental)*	2. Variety*
3. Cure Method (Select only one)* <input type="checkbox"/> Air <input type="checkbox"/> Steam <input type="checkbox"/> Fire	4. Heat Source (e.g., propane, wood)*
<input type="checkbox"/> Sun <input type="checkbox"/> Flue <input type="checkbox"/> Other (Specify): _____	
5. Describe any DNA recombinant technology used to engineer the tobacco (If none, enter "none")*	
C. Complex Purchased Ingredients	
Enter the manufacturer's name and the unique identifying item name and/or number used by the manufacturer. If you obtain this ingredient from multiple sources, enter all identifying information for each source below. You may use continuation pages as necessary.	
1a. Manufacturer Name*	1b. Unique Identifying Item Name and/or Number*
FORM FDA 3742 (11/09) Page 5	

SECTION IV - INGREDIENT LISTING (Continued)		
Product Name*	Ingredient Name	
John's Special Blend (KS)	High fructose corn syrup	
FDA-Assigned Tracking Number	Ingredient Number (IN#)	
	2	
PART 1 (Continued)		
C. Complex Purchased Ingredients (Continued)		
2. Is this ingredient made to your specifications?* <input type="checkbox"/> Yes (See immediately below) <input type="checkbox"/> No (Skip to Part 2)		
If Yes, enter each specified ingredient by IN#. * You may use continuation pages if necessary. We also request that you attach specifications for this ingredient (e.g., release specifications).		
IN#	IN#	IN#
IN#	IN#	IN#
PART 2: INGREDIENT DETAILS		
1. Quality (e.g., % purity, published standard)		
Meets Food Chemicals Codex specification		
2. Expected Function(s) (Identify all that apply; use Appendix A for list of functions.)		
Humectant	Casing	Reaction product precursor
3. Part ingredient is added to (Check all that apply)*		
<input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify): _____		
<input type="checkbox"/> Filter <input checked="" type="checkbox"/> Tobacco (Specify): Applied only to burley tobacco prior to redrying		
PART 3: QUANTITY		
1. Quantity*		1a. Unit* <input type="checkbox"/> g <input checked="" type="checkbox"/> mg
49.68		<input type="checkbox"/> mcg <input type="checkbox"/> ng <input type="checkbox"/> pg
		1b. Reported per* <input checked="" type="checkbox"/> Unit of Use <input type="checkbox"/> Gram of Product
2. Enter targeted outcome if variable amount has been added to achieve specific product characteristics (e.g., achieve pH of 7.1).*		
N/A		
3. If you approximated quantity at or near "0," enter limit of detection.*		3a. Unit* <input type="checkbox"/> g <input type="checkbox"/> mg
		<input type="checkbox"/> mcg <input type="checkbox"/> ng <input type="checkbox"/> pg
PART 4: ADDITIONAL COMMENTS		
Please provide any additional information or comments about this ingredient, including any internal identifying numbers. If you are adding, deleting, or changing the quantity of an ingredient, please explain why the change was made. If changing the quantity of an ingredient, you are also required to include the quantity prior to the change.		
Part of the HFCS is expected to react with the free amino acids in the burley tobacco to yield a series of Maillard reaction products. It is believed that when the tobacco is smoked, these Maillard reaction products decompose to heterocyclic nitrogen compounds that increase the tobacco taste of the smoke. There are no standard methods available to provide quantitative information on the levels of Maillard reaction products in the fully processed tobacco blend.		
FORM FDA 3742 (11/09) Page 6		

If we report our ingredients, are we done?

- Product in the marketplace should reflect disclosures
 - ❑ While analytical data from a market pick up will rarely be match disclosure data they should be close
 - ❑ Getting certificates of analyses (C of A's) for purchased items will help ensure you are making what you say you are making
 - ❑ It is your job to verify that materials you are using have same composition as on certificates of analyses
 - You need to get analytical data from suppliers that can be verified
 - You will likely want to use qualified laboratory (e.g., ISO 17025) for analytical data needed to verify C of A's
 - ❑ The FDA may consider out-of-specification product to be misbranded and/or adulterated
 - ❑ Consumers like correctly manufactured product

Can we do all this and still satisfy our stakeholders?

- Meeting FDA rules and regulations will add costs
 - We need to work together to minimize duplication of effort and the added costs of duplicated effort
 - Facilities inspection
 - Employee training
 - On-line and off-line measurement systems
 - Data reporting systems (electronic, paper reports)
 - We can get better pricing and likely better quality services by working together
- Each company can pay for everything or we can share the costs of common tasks and only pay for our own for unique elements

Conclusions

- The time to get started on meeting FDA rules and regulations is now, not later
- FDA ingredient reporting requirements are much more complex than those for DHHS and other entities
 - Need to start now to get information you will need
 - Need to arrange for technical and legal assistance you will need to complete ingredient reports
 - Need to ensure products you are making are congruent with your disclosures
- By working together, we can reduce costs and increase consumer satisfaction