

TTB and FDA:

Working Side by Side to Regulate Alcohol Beverages



Wednesday, March 10, 2010

NABCA 17th Annual Symposium on
Alcohol Beverage Law & Regulation



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Moderator

Robert C. Lehrman

- Attorney at Lehrman Beverage Law, PLLC
Washington, DC
 - Have handled closely related issues for many of the subject companies and brands but not speaking on behalf of anyone else today
- Moderator
- Overview and TTB



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Overlap Issues

Places where TTB and FDA intersect

- Ingredients, Sweeteners, Guarana, Taurine
- Vitamins, Anti-Oxidants
 - TTB vitamin announcement, February 25, 2010:
www.ttb.gov/main_pages/defer-review-abf.shtml
- Serving Facts, Allergens
- ***Caffeine-Alcohol Beverages ("CABs")***
 - A regulatory tempest: TTB, FDA, State AGs, FTC, CSPI, DC Court, Cities, several state legislatures

CABs



"I try to keep my coffee buzz going till the Martini buzz kicks in."

Panelist 1

Marlene Trestman

- Special Assistant to the Attorney General,
State of Maryland
- State Issues



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Panelist 2

Martin Hahn

- Partner, Hogan & Hartson
Washington, DC
- FDA Issues



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Panelist 3

R. Scott Winters

- CEO, P.I.N.K./Prohibition Beverage Inc.
- Ph.D. in Bioinformatics, Evolution
- The perspective from a business owner, scientist, and brand owner



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Back to the 1930s



- **FAA Act 1935** clearly directs ATF/TTB to handle alcohol beverage labeling
- But **FDC Act 1938** directs FDA to handle "food" ("articles used for food or drink for man")
- "there is an actual or apparent **overlap** of jurisdiction ... between two agencies."



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Brown-Forman Case 1976



Brown-Forman v. Mathews, 435 F. Supp. 5 (W.D. Ky. 1976)

- B-F, DISCUS, WI, NABI asked for relief, to avoid two different regulatory systems from two different agencies
- “we are fully convinced that it was Congress’ intention to place exclusive jurisdiction to regulate the labeling of alcoholic beverages in BATF.”

MOU 1987



Memorandum of Understanding ("MOU")

- Between FDA and ATF/TTB, 1987
- FDA has authority over adulteration, including alcohol beverages
- TTB has authority over labeling
- If FDA finds a problem with an ingredient in alcohol beverages, TTB should take the lead

Testing the MOU

TTB has allowed caffeine in alcohol beverages for many decades

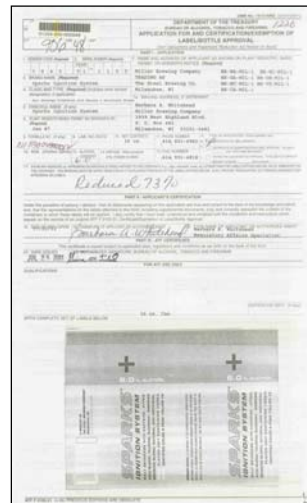
- Kahlua-type coffee liqueur
- Products with added caffeine about 10 years



Sparks 2001

Sparks approved 2001

- Beer with added caffeine, guarana, taurine, ginseng
- A lot of issues in one can



FDA Rule on Caffeine

Subpart A—General Provisions

§ 182.1 Substances that are generally recognized as safe.

(a) It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, vinegar, baking powder, and monosodium glutamate as safe for their intended use. This part includes additional substances that, when used for the purposes indicated, in accordance with good manufacturing practice, are regarded by the Commissioner as generally recognized as safe for such uses.

§ 182.1180 Caffeine.

(a) *Product.* Caffeine.
(b) *Tolerance.* 0.02 percent.
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in cola-type beverages in accordance with good manufacturing practice.

For many decades FDA has allowed direct addition of caffeine to foods

- But a difficulty is that the rule (21 CFR § 182.1180) explicitly allows it only in “cola-type beverages”
- Perhaps not okay in Mountain Dew, Sunkist, Red Bull
- Or vodka, beer, wine, etc.



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TTB Formula 2/2009



About a year ago

- No direct reference to FDA caffeine rule



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TTB Formula 12/2009



A few weeks after FDA action

- "This product contains added caffeine and should not exceed 200 ppm contained in the finished product."
- "This formula is approved pending final determination from [FDA] regarding the addition of caffeine to alcohol beverage products."
- "This approval is granted under 27 CFR Parts 7 and 25 and does not in any way provide exemption from or waiver of the provisions of [FDA] regulations relating to the use of food and color additives in food products."

TTB Labels

Thousands of TTB products with caffeine

- And hundreds with direct caffeine
 - List at www.bevlaw.com/news-caffeine.php#caflist
- FDA only looked at about 30



Vodka with Caffeine



Beer with Caffeine



Wine with Caffeine



Dr. O'Brien and CSPI 2008



The Dr. O'Brien study published at *Academic Emergency Medicine*, 2008

- www.udetc.org/documents/CaffeinatedCocktails.pdf
- CSPI sued Miller in DC Superior Court, December 2008
 - Alleged that Sparks is "poisonous" and unsafe
 - Stimulating ingredients in alcohol beverages violates the Federal Food, Drug, and Cosmetic Act

AGs

About a dozen state Attorneys General took on Miller and A-B in 2008

- Made them stop selling Sparks (with caffeine), Bud Extra and Tilt
- WSJ says they are now after smaller brands, and pressing the federal government



FTC Action 2009



In June 2009, the FTC pressed Constellation Brands to stop selling Wide Eye

- Liqueur with caffeine
- Ads suggest alertness
- Can't be substantiated

TTB Rule on Caffeine

Regulations.gov Monday, December 7, 2009 Unified Agenda

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Department of the Treasury (TREAS)
Alcohol and Tobacco Tax and Trade Bureau (TTB) RIN: 1513-AB10
[View Related Documents](#)

Title: Labeling and Advertising of Alcohol Beverages That Contain Caffeine, Vitamins, and Minerals
Abstract: TTB is seeking comments on various issues related to the labeling and advertising of alcohol beverages that contain caffeine, vitamins, and minerals.

Priority: Substantive, Nonsignificant **Agenda Stage of Rulemaking:** Pre-rule
Major: No **Unfunded Mandates:** No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the [Code of Federal Regulations](#).)
Legal Authority: 27 USC 205
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	06/09/2010	

In recent years TTB has said it plans to initiate new rules on caffeine, vitamins, and minerals

FDA Moves

November 13, 2009 letters to about 30 brands

- No food additive rule allows caffeine added to alcohol beverages
- Unapproved food additive is deemed "unsafe"
- Any food that contains it is "adulterated"
- Need evidence that this use of caffeine is GRAS or prior sanctioned, within 30 days
- Exempts Kahlua-type beverages



TTB Reacts



TTB set forth policy in November 18, 2009 Newsletter, five days after FDA letters

- Met with AGs and FDA
- 1987 MOU still in force, TTB has followed it
- TTB asked FDA to clarify (in 2008), no objection up to 200 ppm
- TTB looks forward to FDA determination

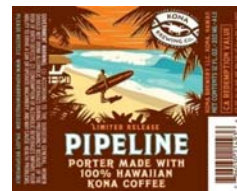
Suggestions

Dangerous, if coffee liqueur and coffee porter are not?

- What's been consumed more: near in time/place, widely/longer?
- Ban coffee, cola, Red Bull from licensed premises?

Need more studies on both sides

- Current studies focus on self-mixing (not the TTB/FDA pre-mixed products)
- Focus on sensation-seeking young adults not general
- Ignores Rum & Coke, Bourbon & Coke, Coffee Liqueur, Irish Coffee



Suggestions

Caffeine limits and better labeling, rather than one extreme (ban) or the other

- Why should anyone have to guess how much caffeine is/isn't in Kahlua or a coffee porter?

Ban fixes nothing



Next

More information at:

- www.bevlaw.com
- www.bevlaw.com/bevlog
(blog about TTB label trends)
- rclehrman@bevlaw.com

On to Marlene Trestman