The Food & Drug Administration’s Involvement in the Brewing Industry

August 9, 2012

Peggy Binzer & Marc Sorini
McDermott Will & Emery LLP
Who is the FDA?

- A part of the Department of Health and Human Services
- Authority comes from the Federal Food, Drug & Cosmetic Act (“FD&C Act”)
- Under the FD&C Act, FDA regulates drugs, foods and cosmetics, principally for labeling and safety issues
FDA’s Basis for Jurisdiction

- Beer falls within the definition of “food” under the FD&C Act
  - Bioterrorism Act regulations explicitly mention alcohol beverages in their “food” definitions
  - Food Safety Modernization Act (“FSMA”) and the Food and Drug Act Amendments includes alcohol in their “food” definitions

THUS, FDA clearly has some authority over beer and breweries

- But how much . . . ?
Arose from a 1970s initiative by FDA to impose ingredient labeling on alcohol beverages

Then, as now, regulations under the Federal Alcohol Administration Act (“FAA Act”) (then administered by ATF, now TTB) did not require ingredient labeling

COURT HELD that, where the two agencies’ regulations clashed, the FAA Act regulations (under ATF/TTB) prevail

Case might not be followed by other courts
TTB responsible for making and enforcing labeling regulations applicable to beer
- Exception: Beer made without hops and/or malted barley fall outside TTB’s labeling jurisdiction

FDA supports TTB with health hazard evaluations, laboratory assistance and the like

TTB has “primary responsibility” for recalls, even if the recall arises from FD&C Act issues

TTB will “consult” with FDA in recall situations

Agencies’ labs will consult with one another
What’s Left for FDA?

TRADITIONALLY
- Regulation of ingredients and additives (e.g., GRAS status)
- Good manufacturing practices

NEW AREAS
- Registration of facilities, pre-import notification and recordkeeping under the Bioterrorism Act
- Reportable Food Registry
- FSMA requires Hazard Analysis & Critical Control Points (“HACCP”) plan
FDA Involvement in Breweries – FDA Ingredient Safety Standards

- Every ingredient used to produce a food (including beer and other alcohol beverages) must be permissible under FDA standards
  - Food made with an impermissible ingredient is “adulterated” under the FD&C Act

- The safety of a relatively small percentage of food ingredients is established through FDA pre-market approval
  - This is a very expensive, time-consuming process
  - Backlog at FDA means that pre-market approval petitions take years
  - Pre-market approval usually reserved for truly novel, non-traditional ingredients (e.g., new non-nutritive sweeteners)
Safety of most food ingredients established by ingredient being “generally recognized as safe” or “GRAS”

Producers can show an ingredient is GRAS
- By scientific evidence, similar to what is needed to obtain FDA pre-market approval
- By demonstrating a history of safe use prior to 1958

For brewers, the Beer Institute’s *Adjunct Reference Manual* provides a helpful compilation of materials brewers deem GRAS for use in brewing

TTB also has a process for brewers to pre-clear the use of new adjuncts
Banned Alcohol Energy Drinks

- FDA will use its Food Additive Authority to remove unsafe alcohol products from the marketplace
  - In 2010, FDA issued warning letters to four caffeinated alcohol beverage companies warning that caffeine added to their malt beverages constitutes an “unsafe food additive.”
  - Many products (Four Loko, Joose) on the market were reformulated in response to regulatory pressure

- FDA drew a very fine line that targeted caffeinated malt beverages, but not more traditional products made with coffee, tea, etc.

- FDA coordinated its letters with simultaneous action by the Federal Trade Commission (“FTC”) and TTB
GMPs are used to determine if

- food has been manufactured under conditions that are unfit for food; or

- food has been prepared, packed, or held under insanitary conditions such that it may have become contaminated with filth or be injurious to health
FDA GMPs (cont.)

The areas addressed by the GMP regulations include:

- **Personnel** - Disease control, cleanliness, education and training
- **Plants and Grounds** - Kept in a condition to protect against contamination
- **Sanitary Operations** - General maintenance of the physical plant, cleaning and sanitizing substances, pest control, sanitation of food contact surfaces
- **Sanitary Facilities and Controls** - Water supply, plumbing, sewage disposal, hand-washing, trash removal
- **Equipment and Utensils** - Adequately cleanable, properly maintained, designed, constructed and used to preclude adulteration
- **Production and Process** - Natural or unavoidable defects in food for human use that present no health hazard
- **Raw materials and other ingredients** - Manufacturing operations, warehousing and distribution control
- **Defect action levels**
Handling an FDA Inspection

- Ask for credentials and FDA Form 482 (Notice of Inspection), and cooperate with the inspection
- Have a designated, knowledgeable person accompany the inspector
- Don’t hesitate to ask questions
- If the inspector takes samples, get splits and an FDA Form 484 (Receipt for Samples)
- Discuss the inspector’s findings in an exit interview and obtain any FDA Form 483 (Inspectional Observations)
- Respond to any Form 483 orally and in writing
Consequences to Inspection

- Form 483 will specify that you have 15 days to tell FDA how you will respond to the observations.
- If you do not respond, you may receive a warning letter requesting a formal response.
- If FDA finds your response inadequate, it can exercise a host of regulatory powers:
  - Injunction preventing product from entering interstate commerce
  - Seizure of product
  - Administrative detention of product
  - Mandatory recall
  - Civil or criminal penalties
Trends and Developments

- FDA appears more interested in regulating the alcohol beverage industry than ever before
  - Bioterrorism Act rulemakings
  - Increased visits to breweries and wineries
  - Allergen/Gluten labeling
  - Restaurant menu labeling rules

- Industry uneasy about these developments
  - In the past, industry “conventional wisdom” preferred “the devil you know” (ATF/TTB) to FDA
Bioterrorism Act of 2002 has four major components

1. **Registration of facilities**
   - Under the FSMA, all food facilities that are required to register will now need to submit a biennial renewal registration
   - FDA announced re-registration will occur during the three month window beginning October 1 and ending December 31, in even numbered years

2. **Pre-import notification**

3. **Detention of foods**

4. **Recordkeeping requirements**
Bioterrorism Act – Registration

- Simple registration on-line
  - Unlike TTB and state licensing, FDA does not review and approve or reject
  - No fee involved

- Domestic and foreign facilities must register

- Changes in information must be reported to FDA
Bioterrorism Act – Recordkeeping

- No need to duplicate existing (e.g., TTB-required) recordkeeping systems
- “One-up, one-down” system
  - One-up: Food producer, handler or transporter must keep records on source of food and food ingredients
  - One-down: Food producer, handler or transporter must keep records on destination of food and food ingredients
- Records must be made available to FDA on 24-hours notice
Allergen and Gluten Free Labeling

- Food Allergen Labeling and Consumer Protection Act (passed in 2004) amends the FD&C Act to require clear, plain-language disclosure of the “big eight” food allergens
  - (1) milk, (2) eggs, (3) fish, (4) crustacean shellfish, (5) tree nuts, (6) peanuts, (7) wheat, and (8) soybeans
  - Permits gluten-free labeling

- Already applies to products labeling under FDA rules, such as low-alcohol wines (cider, etc.) and beers made without malted barley and/or hops

- For products whose labeling is regulated by TTB, Congress said it “expects” TTB to “determine how, as appropriate, to apply allergen labeling of beverage alcohol products”

- TTB has yet to finish its allergen rulemaking
Gluten Free Labeling

- Many gluten-free beers are made without malted barley and, thus, fall within FDA’s labeling jurisdiction.
- FDA has had a proposed gluten-free labeling rule pending since 2007.
- Proposed rule establishes a 20 ppm maximum threshold for labeling products gluten free.
- In a 2011 re-opening of the comment period on the proposed rule, FDA expressed doubts about the ability to test for gluten in fermented foods (like beer).
- “Competitive R5 ELISA” test promising at accurately detecting gluten in fermented foods.
Reportable Food Registry

Electronic reporting system on FDA’s website

- Producers, bottlers, and those operating warehouse facilities must report within 24 hours the release of an “adulterated” food when there is a reasonable probability that the use of, or exposure to the adulterated food article will cause serious adverse health consequences or death to humans or animals.

- Reporting is unnecessary if food article remains in the possession and control of the manufacturer.

- Reports are public.
Food Safety & Modernization Act ("FSMA")

- Sweeping expansion of FDA’s powers with the goal of ensuring food safety from farm to table
- Fees for re-inspection, mandatory recall (if company fails to comply), and new import programs
- Mandated inspection frequency: All high-risk domestic facilities must be inspected within five years of enactment and no less than every three years thereafter
- Records access: FDA will have access to records, including industry food safety plans and the records firms must keep to document implementation of their plans
- Regulations implementing FSMA are forthcoming
FSMA Requires HACCP

FDA is drafting regulations for all food facilities to implement written preventive control plans, including:

- Evaluating the hazards that could affect food safety
- Specifying what preventative steps or controls will be put in place to significantly minimize or prevent hazards
- Specifying how the facility will monitor these controls to ensure they are working
- Maintaining routine records of monitoring, and
- Specifying what actions the facility will take to correct problems that arise
Questions for Peggy or Marc?

Thanks for Your Time & Attention