

Food & Marketing Law Update

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FDA to Ban Sale of Dietary Supplements Containing Ephedra

*Is "re-regulation" of the dietary supplement industry on the horizon?
Bioterror detention for non-compliance?*

In a precedent setting action the FDA announced on December 30, 2003 that it will issue a rule to ban the sale of dietary supplements containing ephedra. The FDA also said it is sending letters to 64 firms which distribute or manufacture dietary supplements containing ephedra telling them that the FDA will begin enforcing the ban as soon as the rule becomes final; thereby, apparently precluding any phase out of banned product inventories after that date.

The FDA, which for years has proposed restrictions on the marketing of dietary supplements containing ephedra, is basing its action on a RAND corporation study that the FDA commissioned. Based on the results of the study, the FDA has concluded that ephedra containing dietary supplements represent an "unreasonable risk of injury or illness" under the federal Food, Drug & Cosmetic Act. The letter to the distributors states that FDA will begin enforcing the rule 60 days after it becomes effective. The 60 day delay is to allow for congressional review or as it is more commonly called "congressional veto." According to an FDA Q&A release, the proposed rule will be published in the Federal Register in "a

few weeks" for public comment. The Q&A does not state when FDA anticipates that it will issue a final rule. In addition to the 60 day congressional veto period, completion of the rule making process will probably take several months.

Since 1997 the FDA has considered proposals to place limits on the use of ephedra in dietary supplements, but FDA action has been limited by the restrictions in the 1993 Dietary Supplement Health and Education Act, commonly known by its acronym DSHEA. Under DSHEA products marketed as dietary supplements are generally subject to a much lesser degree of FDA oversight than products that are marketed as food or drugs. Several public interest groups have vehemently opposed DSHEA and it is expected they will use ephedra as a spring board to call for broad changes in the law.

The FDA's Q&A also stated that it did not classify ephedra containing dietary supplements as an "imminent hazard to the public health," because the classification of a substance as an "imminent hazard" is subject to a much higher legal standard

FDA's Ephedra Ban (cont'd on p.3)

It's 1:00 AM, Do You Know Where Your Distressed Product Is?

We seriously doubt whether there is a company in the food or dietary supplement business that at one time or another has not faced the issue of how to dispose of an out-of-spec product. You're operating your plant by rigorously following GMP's and have an excellent HACCP program and low and behold the QC department discovers that one or more lots doesn't taste, smell or look quite right, or worse yet the product is mis-branded or adulterated. Fortunately, you still have control over the all of the suspect produc-

tion. Now, what do you do with it?

Well, depending on the condition of the product, there is a menu of possibilities:

- The dump
- Cattle feed
- Reprocessing
- Relabeling
- Distribution out of the country
- Distribution through domestic distress and

Where is Your Distressed Product? (cont'd on p.2)

COMMENT: Get Ready for Lots More Regulation

Libertarian types and others who are philosophically opposed to government regulation should skip the rest of this article because we are going to make what we think are some less than startling predictions concerning the immediate future of the regulation of the food and dietary supplement industries in the United States. In two words: "Lots more."

The areas of increased regulation that are either here or may undergo significant development during 2004 are:

Food Security

- Implementation of FDA Bioterrorism Rules regarding ingredient and product tracking and administrative detention.
- Expansion of the use of Bioterrorism Rules, such as administrative detention, to pedestrian cases of food borne illness and suspected food adulteration.
- Bioterrorism rules for products within USDA jurisdiction

Obesity

- More on-label disclosure requirements for "bad" nutrients in products á la trans fat
- Warning labels on foods (á la cigarettes) that are high in fat, cholesterol, calories, etc.
- Limitations on advertising and cross-promotional activities of "fast" and "junk" food when directed at children
- Labeling requirements for "fast food" and warning notices (á la California Prop. 65) for fast food restaurants
- Government sponsored television commercials demonizing junk food manufacturers (California only)
- More private (mostly class action) lawsuits

Dietary Supplements

- More challenges by the FDA and private litigants against dietary supplement manufacturers for marketing unsafe or ineffective products.
- Proposals to revise the Dietary Supplement Health and Education Act ("DSHEA") to put some "teeth" back into FDA regulation of dietary supplements

Where is Your Distressed Product? (cont'd from p.1)

close out "big box" stores

Of course, if the product's adulterated the only choice you have is to dump it. If it's misbranded you will need to either dump it or relabel it. Even if the product is legally saleable as packaged but not up to your quality standards, you still face the issue of trying to recover at least some of your production costs without the product getting into the channels of distribution where it might reach those unforgiving customers with whom you have labored so long and so hard to build up a brand name franchise. On the other hand, once the distressed product is sent to a third party, you no longer have physical control, and who knows, where it might finally wind up. Therefore, whenever you are in a product disposal situation you must have trust and confidence that the disposer will handle the product exactly as promised and that load of off color juice will in fact go to

GMO's

- State labeling requirements (again, á la Prop. 65) to identify raw and processed foods containing GMO's
- Use of zoning and environmental laws to restrict farming of GMO crops and production of GMO livestock. (There is a GMO farming ban on the March 2004 ballot in Mendocino County, California.)
- Outright bans on the sale of GMO products based upon the states' police powers.

Note that our predictions are not dependant on which political party controls either the White House or the Congress. The recent growth of federal regulations and regulatory activities affecting the food and dietary supplement industries has occurred during a "conservative" Republican administration with the Republicans controlling both houses of Congress. A Democratic administration will undoubtedly be much of the same, just maybe more of it. Moreover, even if the regulators are sympathetic to industry issues (FDA has tried to put a "happy face" on the Bioterrorism Rules and USDA has been very cool to COOL), inevitably political pressures molded by a frequently not very well informed public opinion that assumes perfect food safety is both achievable and affordable and, sometimes, court decisions, may force the regulators to take off the velvet glove and use the iron fist.

Therefore, the issue facing you isn't whether regulation is going to increase and get much more complex, it will. The issue is how will you deal with it? Will you either individually or through your trade associations lobby for legislation and rules that are not unduly burdensome and are cost effective? Will you develop and implement on a timely basis compliance programs for your company that meet regulatory requirements? Will you outsource some regulatory compliance activities and to whom? Will you be proactive or wait until what will probably be the every less forgiving FDA, USDA or state inspector orders you to get into compliance? Will a federal or state official escort you off your business premises while wearing metal bracelets? ■

Mexico and not be sold to an unwitting buyer at Von's or Whole Foods, who will be lighting up your phones with customer complaints.

Comment

If you are unfortunate enough to be in a product disposal situation, Zackler & Associates can help you by examining the available disposal alternatives, locating reputable companies that will dispose of the distress product as promised, ensuring that your agreements with the disposal firm says what it should say to protect you and your brand, and auditing the disposal process so that you, your risk manager and any government types that might be involved are happy. At 1:00 AM you will be sound asleep knowing that your distressed product is exactly where it should be whether it's the land fill, the cattle ranch or the grocery store in Guadalajara. ■

than the "unreasonable risk" classification, and the FDA was "less confident" that an action under the imminent hazard standard would be sustainable. Use of the "imminent hazard" standard would have expedited the rule making proceeding to ban ephedra's use.

Comment

Not addressed in the FDA's materials is the possibility of the agency taking action under the administrative detention authority that was given it in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act"). Although the FDA has delayed at least until March 2004 final rules implementing its detention authority, such rules are not required by the Bioterrorism Act as a prerequisite for the FDA using its detention authority. As readers of prior issues of *Food & Marketing Law Update* know, the FDA's detention authority is an in-house administrative action that does not require rule making or initial judicial approval. The standard for exercising this authority is stated in the Bioterrorism Act is that the FDA has credible evidence or information indicating that an article of food, which includes dietary supplements, presents a threat of **Serious Adverse Health Consequences Or Death To Humans Or Animals**, fondly known to us and the people who have seen Zackler & Associates' Bioterrorism Act presentation as **SAHCODHA**. The threat need not be related to bioterrorism. Whether or not anyone at FDA ever raised the issue of administrative detention, it's pretty clear to us that although an "imminent hazard" might be SAHCODHA, an "unreasonable risk" is not. ■

Yes, There Are Criminal Prosecutions for Violation of the FDCA Act

Although it's extremely rare, every now and then there is a criminal prosecution for violation of the Food, Drug & Cosmetic Act ("FDCA"). Recently, Robert Lingon, the owner of a health food company, pled guilty to mail fraud for marketing "low fat" donuts that were, in fact, conventional, very high fat donuts. While we doubt that any readers of *Food & Marketing Law Update* would ever engage in an intentional violation of the FDCA, Mr. Lingon's conviction does prompt a few observations:

- Violations of the FDCA can be prosecuted as other crimes such as mail fraud or even racketeering.
- Most criminal prosecutions require willful misconduct; however, the FDCA is written as a "strict liability" statute. (See "Ask Allan" in the Winter 2003 issue of *Food & Marketing Law Update* for a discussion of willful misconduct, strict liability as well as recklessness, and negligence.) Nevertheless, when a strict liability crime is involved, most prosecutors are reluctant to pursue criminal charges because most juries are reluctant to convict a defendant for a "no fault" crime.
- When criminal charges are filed we are not talking about technical misunderstandings of FDA rules or "pushing the envelope" on issues such as health claims on a label. Rather we're talking about deliberate misbranding or use of illegal or dangerous ingredients. For

example, some of our readers may recall that two executives of the Beechnut Baby Food Co. went to prison several years ago for deliberately using colored sugar water in what was suppose to be apple juice.

Of course, there is always the potential for civil liability both in terms of the FDA's authority to seek injunctive relief and third party product liability lawsuits. These types of civil actions are usually based on strict liability.

Comment

Although we don't expect to see very many (if any) food or dietary supplement executives or their companies doing the "perp walk," in the age of bioterrorism and BSE we expect that some cases (which in the past would have been handled using only civil remedies) in the future may result in criminal prosecution. ■

Matt Frank Leaves Zackler & Associates

Matt Frank, who has been with Zackler & Associates since February 2000, has left our firm at the end of January to follow the Yellow Brick Road to Topeka, Kansas where he will assume the position of Regulatory Counsel at Hills Pet Nutrition, Inc., the pet food division of the Colgate-Palmolive Company. Hills markets the Science Diet brand of pet food. Allan and Steve will continue to work on the projects that Matt has been handling for various clients of Zackler & Associates. We wish Matt well in this next phase of his career. You can continue to contact Allan at azackler@foodlaw.com and Steve at sweinstein@foodlaw.com. ■

How Now Mad Cow? (cont'd on p.3)

green onions resulted in at least three deaths.) Meat producers who sell organic and free-range cattle are pointing out that their livestock are not given feed that contains animal tissue. Perhaps the biggest marketing opportunity is for the proponents of country of origin labeling ("COOL") who now face a two year legislative moratorium on COOL's originally scheduled implementation date of September 1, 2004.

Finally, as we go to press, the FDA has announced its own set of rules which will prohibit the use of material from downer cattle and the use of SRM's in the food products it regulates. The FDA will also prohibit the use of certain animal materials in animal feed.

Comment:

In the article in this issue on ephedra we discussed the possibly of FDA using its new police power under the Bioterrorism Act to detain product. No such discussion will occur here because meat and other products subject to the exclusive jurisdiction of the USDA are not subject to the FDA's Bioterrorism Rules which include facility registration, import pre-notification, tracking record keeping as well as administrative detention. Although COOL was originally conceived for commercial (i.e. "Buy American") purposes and not as a food safety law, perhaps its proponents will recast it as a public health measure that would, at least in part, fill this gap in the Bioterrorism Rules. ■

Food & Marketing Law Update

The information in *Food & Marketing Law Update* is general in nature and not intended to be relied upon as legal advice. Zackler & Associates will be pleased to privately discuss with you in greater detail the information in this newsletter including its application to your specific business needs. Of course, we welcome your comments and suggestions.

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- Drug, Cosmetic & Medical Device Issues
- Energy Issues
- Distribution Law

HOW NOW MAD COW?

COOL Components, PETA and organic type meat producers see marketing opportunity

Don't forget to hold the green onions.

The most famous (but unidentified) cow since Mrs. O'Leary's has caused significant policy changes at the USDA and created a public, or at least a media, frenzy of pandemic proportions, although no human deaths or illnesses in the United States or Canada have been traced to bovine spongiform encephalopathy (BSE), the scientific name for "mad cow."

On December 30, 2003, a busy day for federal food regulators (see article on ephedra in this issue), Secretary of Agriculture Ann Veneman announced some immediate changes in the federal meat inspection program that affect only cattle. According to Veneman these changes had been "under consideration" for several years:

1. "Downer" cattle are banned from human consumption.
2. USDA inspectors will conduct pre-slaughter ("ante-mortem" in USDA speak) inspections for indications of BSE in addition to post slaughter BSE inspections.
3. BSE tested cattle will not be marked "passed" until negative test results are in fact received. (Duh!!!)

4. Prohibit the use in the human food supply of (a) certain nervous system cattle parts and related organs (known as Specified Risk Materials or "SRM's") from cattle over 30 months of age and (b) the small intestine of all cattle. The regulations will also prohibit the use of some of these parts in advanced meat recovery (AMR).
5. Prohibit the use of air-injection stunning to prevent brain material from infecting any other parts of a carcass
6. Prohibit the use of mechanically separated meat in human food.

With the exception of Item 3, the above changes were published in the Federal Register on January 12, 2004 as "interim rules" that will become effective 90 days after publication. Item 3 is an "interpretative rule" that became effective upon publication, also on January 12.

Meanwhile, other groups with meat related agendas have jumped into the BSE fray. Not surprisingly, PETA is using BSE to promote veganism. (One should recall that veganism is not some sort of foolproof protection to food borne illness. Last November, a Hepatitis A outbreak linked to