Today’s top regulatory considerations for the sports nutrition industry

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A Tricky Business

• Bigger/Stronger/Faster
• Consumers demand Cutting Edge!
• Sports Performance-Enhancing and yet....
• Under greater scrutiny due to the prohormone days (remember andro)?
What’s *in* the bottle?

Regulatory requirements for sports nutrition *ingredient* compliance
“Dietary Supplement” Ingredients

• A vitamin;
• A mineral;
• A herb or other botanical;
• An amino acid;
• A dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
• A concentrate, metabolite, constituent, extract, or combination of the preceding substances

• If your ingredients fit the above definitions...
• Are they “New Dietary Ingredients” in need of an NDI Notification?
New Dietary Ingredients

• A dietary ingredient not marketed in the U.S. as a dietary supplement or as an article for use in food before October 15, 1994.

• Must show why the new dietary ingredient will reasonably be expected to be safe under the conditions of use.

• Submit NDI notification to FDA 75 days before going to market.

• Sports nutrition market history of not filing NDIs... 😞

Non-Compliant Ingredients

• Ingredients not meeting the definition of a “dietary ingredient” under DSHEA will continue to be vulnerable to action by FDA [also from class action consumers and competitors (Lanham Act suits)].
Cannabidiol (CBD) Oil hits the Sports Nutrition Market!

- Cannabidiol (CBD) is one of over 100 cannabinoids naturally found in cannabis plants. Cannabis plants include both Marijuana and Hemp.

- CBD Oil may have benefit as a recovery supplement – may help reduce inflammation, support muscle and joint health, lower stress and anxiety, support better sleep, and aid with digestion.

- So, CBD and other “Phytocannabinoids” are being added to popular Sports Nutrition products such as Whey Protein and BCAAs to support post workout recovery.
December 20, 2018: President signed the 2018 Farm Bill.

- Exempts “Hemp” from the definition of “marihuana”
  - “Hemp” and Cannabinoids derived from hemp are no longer controlled substances.
- THC limit for Hemp is “not more than 0.3 percent on a dry weight basis.”
- However ... FDA (so far) says CBD is *not* a dietary ingredient, dietary supplement, or food additive
  - noting it was the subject of substantial clinical investigations by GW before being marketed as a food or dietary supplements).
- But ... the market seems to be ignoring FDA and is flooded with supplement products containing CBD. And recent statements from FDA suggest they may be softening on CBD...
CBD and Drug Tested Individuals

• THC is a Schedule 1 Drug and also prohibited by WADA, NCAA and other testing organizations.

• Many CBD companies state that their product contains less than 0.3% THC but do not test them. What if the product, or a certain batch, contains more THC than listed on the label?

• What if the athlete/employee is taking multiple servings per day? Is this enough THC to cause a positive result in a drug tested athlete or employee?

• Can THC content increase over time in CBD products stored under certain conditions?
Bodybuilding Products

- Consumers want “cutting edge” products
- Starting in late ‘90s, steroidal ingredients hit sports nutrition market
- Androstenedione (‘andro”) and a host of chemical cousins
- Many were synthetic – not DSHEA compliant!
Prohormones


• Cracked down on the over-the-counter “prohormone” segment of the sports nutrition supplement market – expanded definition and listed more 25 steroidal compounds as anabolic steroids.

• Crushed the prohormone market.
So, along come SARMs

• **Selective Androgen Receptor Modulators**
• **Synthetic, non-steroidal chemical compounds**
• Selectively bind to the androgen receptors in skeletal muscle and bone rather than androgen receptors in other sites, such as the prostate, reproductive organs, scalp, etc.
• **Appeared on sports nutrition market in last few years.**
• MK-2866, GTx-024, Enobosarm;
• Developed by GTx, Inc. as a potential treatment for Stress Urinary Incontinence and for breast cancer;
• Effective daily doses: 3mg improved SUI in women; 9mg and 18mg proved effective for breast cancer;
• Popular for bodybuilders/athletes to build muscle and strength – but doses range from 25mg to 100mg per day!
SARMs as a Dietary Supplement?

• Currently, SARMs are not a controlled substance.
• Do not fit the definition of an “anabolic steroid” under DASCA.
• Last year, Senators Hatch and Whitehouse introduced “The SARMs Control Act of 2018” seeking to give DEA the authority over SARMs as Controlled Substances.
• The bill did not pass (yet).
• So, are SARMs legal as supplements...?
SARMs: Legal Supplement?

**FDA says no:**
- Doesn’t meet the definition of a dietary supplement ingredient (vitamin; mineral; herb; etc.)
- Investigational new drugs - SARMs were not marketed as dietary supplements or foods prior to their authorization for investigation as a new drug (Ostarine®).
- Safety has not been shown – Risk of heart attack, stroke, and liver problems.
- Prescription drugs - Not safe for use without the supervision of a medical professional.

• Marketers (companies and individuals) have faced *criminal and civil charges* for “defrauding the consumers and/or the government” for falsely calling it a dietary supplement or a “research chemical not for human use.”
“Stimulant Whack-A-Mole”

- FDA banned Ephedra and Ephedrine products sold as dietary supplements in 2004 after voluminous reports of adverse health effects.
- After Ephedra was banned, demand for an alternative grew and companies searched for a replacement.
- Enter DMAA – also known as 1,3-dimethylamylamine, methylhexanamine or geranium extract.
DMAA

- FDA says supplements containing DMAA are illegal and can lead to health risks such as increased blood pressure, shortness of breath and heart attacks and sent warning letters to companies notifying them to remove and reformulate products containing DMAA.

- FDA states that DMAA is not considered a Dietary Ingredient because:
  - Synthetically produced
  - Not marketed before 1994 (new dietary ingredient)
  - NDI notification never filed
  - No evidence of safety to establish legality
Other Fat Burners/ Stimulants

• Although the battle over the legality of DMAA continues, companies offered the replacement of DMBA (1,3-Dimethylbutylamine or Amp Citrate), a close analogue to DMAA, and then launched BMPEA (Beta-methylphenethylamine).

• FDA sent warning letters to 14 companies regarding DMBA and 5 companies regarding BMPEA, mirroring the DMAA warning letters.

• In 2016, FDA sent warning letters regarding Methylsynephrine (allegedly found in Citrus aurantium) declaring “methylsynephrine in your product labeling as a dietary ingredient causes your products marketed as dietary supplements to be misbranded.”
Tip of the Day on “Edgy”

Ingredients:

• Mama had it right: Honesty is the best policy.
What’s on the bottle?

Regulatory requirements for sports nutrition labelling compliance
Regulations O’Plenty!

• Federal law and regulations dictate labelling requirements right down to font size.
• Claims are regulated by both FDA and FTC – make sure they are substantiated!
• Issues can be tricky – Nutrition Facts panel or Supplement Facts panel? (e.g., intended use of a protein powder).
Testing!

- **What’s *on* the label must be *in* the bottle.**
  - GMPs require testing for Identity, Strength, and Purity!

- **What’s *NOT on* the label **CANNOT** be *in* the product.**
  - Contamination issues!
  - Drug tested athletes demand products that are free of banned substances.
  - Numerous athletes have alleged supplement positives, from Kicker Vencill to Jessica Hardy to Sam Soliman.
1) Contamination of Raw Materials (Ingredients)

- The starting materials in a product may be contaminated, possibly because the raw material supplier also produces banned substances.
2) Contamination During Processing or Post-processing:

- Improper separation of production lines, inadequate use of physical detachments and lockouts, use of staging areas, routine maintenance of manufacturing equipment, or unbiased, third party audit of GMPs.
- Cross-contamination
3) Incorrect Labeling or Packaging

- Products can be packaged from old or other products or placed in the wrong packaging. In other cases, all the ingredients in a proprietary blend might not be declared on the label when they should be.
4) Intentional Tainting

- Athletes may be motivated to intentionally contaminate the product after a positive drug test.
- However, unscrupulous companies may also sometimes intentionally add banned substances to their products in order to add “kick” to a fat burner or muscle-building formula. If detected, the principals of these companies may face criminal prosecution for distributing adulterated and misbranded drugs.
Good Manufacturing Practices

• The US FDA published proposed current good manufacturing practice (GMP) regulations for dietary ingredients and dietary supplements in March, 2003.

• Now finalized, they establish quality control safeguards.

• However, FDA has estimated that about 70% of supplement companies are not compliant with GMPs. [http://www.newsday.com/news/health/fda-official-70-of-supplement-companies-violate-agency-rules-1.5920525](http://www.newsday.com/news/health/fda-official-70-of-supplement-companies-violate-agency-rules-1.5920525)

• Tip: Get a GMP check-up NOW!
Tip of the Day on Testing Products:

• Consider 3\textsuperscript{rd} Party Banned Substance Certification
  • “Seal” shows the product has been tested for banned substances.
  • Organizations include:
    https://www.bscg.org/
    http://www.nsf.org/
    http://informed-choice.org/
Beyond the Feds

How state *legislatures* and *regulators* can impact worldwide businesses
State Laws and Regs

- Federal actions affect everyone in the U.S.
- Bills introduced at the State level typically receive less attention.
- “Not Our State, Not Our Problem”
- California’s Notice of Prop 65 Violation

  • “[Bounty Hunter] has identified violations of [Prop 65] . . . . [Bounty Hunter] intends to file a private enforcement action in the public interest 60 days after effective service of this notice . . . . The Violators violated Proposition 65 because they failed to provide persons handling and/or using these products with appropriate warnings that they are being exposed to these chemicals.”
– Law and Original Purpose

• California’s Safe Drinking Water and Toxic Enforcement Act of 1986
• Companies selling products containing a listed chemical must warn consumers before exposure. New Warning requirements took effect in August, 2018:

![WARNING: This product can expose you to chemicals including [name of at least one chemical], which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information visit www.P65Warnings.ca.gov](image)

• Developed to protect the state’s drinking water supply from contamination with chemicals that cause cancer or birth defects
• Noble goal, but...
– **Metastasis of Law**
  
  • Now includes over 900 chemicals
    
    – E.g., must warn about lead if present in amounts in excess of 0.5 micrograms per day, a threshold as much as 20 times lower than federal/international limits
  
  • Bounty-hunter provision has created an industry where non-profit “environmental” entities test random products and, if they detect excessive levels of chemicals (often lead), sue companies

– **Products at issue:**
  
  • Amino-acid based testosterone boosters
  
  • Nitric oxide vasodilators
  
  • Protein powders
Avoiding Future Problems

– Narrowly tailor warnings and provide them only when product tests above limits of chemicals.
  
  • E.g., place warning on only California-bound products, and only when product tests show it contains above allowable level of contaminants.
  
  • BUT, not always possible to determine where products will be sold.
– Preemptively warn everyone?

• Some companies place the warning on their labels, even if they have no reason to believe their products contain contaminants

• Warning may prevent lawsuits but is alarming to non-Californians, and California government discourages the practice
Defenses

– Fewer than 10 employees exemption:
  • Warning requirements do not apply to companies with fewer than 10 employees
  • Sometimes tough to prove to opposing counsel—typically, show tax returns, sign affidavit/affirmation regarding number of employees
  • **Doesn’t protect you from AG’s office**, which may try to pursue you under other consumer protection laws

– “Naturally occurring” exemption:
  • No warning required if contaminant is naturally occurring in the food—e.g., lead gets into herbal ingredient from environment in which it grows
  • Difficult and expensive to prove
    – Maybe even soil samples needed!
New York’s Creatine Bill

- **New York A.B. 4712** would prohibit any retail establishment from selling dietary supplements that contain creatine to individuals under 18 years of age and impose civil penalties of not more than $500/violation on non-complaint establishments.

- Spurred by article in the *Official Journal of the American Academy of Pediatrics* where researcher posing as 15-year-old athlete asked salesmen at 244 health food stores which supplements he should take. “Health food store employees frequently recommend creatine and testosterone boosters for boy high school athletes.”

- Referred to the Committee for Consumer Affairs and Protection last January.

- ISSN position on safety and efficacy of creatine supplementation: safe and effective with over 1,000 studies conducted [https://jissn.biomedcentral.com/articles/10.1186/s12970-017-0173-z](https://jissn.biomedcentral.com/articles/10.1186/s12970-017-0173-z)
Massachusetts Bill H.1195

• “An Act protecting children from harmful diet pills and muscle-building supplements.”

• “No over-the-counter diet pills or dietary supplements for weight loss or muscle building shall be sold to any person under 18 years of age.”

  • "Dietary supplements for weight loss or muscle building” and “Over-the-Counter Diet Pills” may include, but are not limited to, thermogens, which are substances that produce heat in the body and promote more calorie burning, lipotropics, which are compounds that help break down fat during body metabolism, hormones, including hormone modulators and hormone mimetics, appetite suppressants, or ingredients deemed adulterated under 21 U.S.C.A § 342.

• Could it include Caffeine???
**New York’s Labelling Bill**

**N.Y. A09897**
- Initially introduced by NY Assemblyman Brian Kavanagh as A7607
- Referred to Consumer Affairs and Protection on February 21, 2018.
- Would require dietary supplements sold in New York to place statements on the label that exceed those required under the Food, Drug and Cosmetic Act.

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<thead>
<tr>
<th>N.Y A09897</th>
<th>FDCA</th>
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<tbody>
<tr>
<td>Name and Address of Manufacturer, Packer <strong>AND</strong> Distributor.</td>
<td>Name and Address of Manufacturer, Packer <strong>OR</strong> Distributor</td>
</tr>
<tr>
<td><strong>“Dietary supplements are not approved by the U.S. government for safety and effectiveness before they are marketed.”</strong></td>
<td><strong>“These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”</strong></td>
</tr>
<tr>
<td>The national toll-free telephone number of the American Association of Poison Control Centers.</td>
<td>Address or Telephone number so a consumer can report an adverse event.</td>
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Impact of State Supplement Laws and Regs

• Actions from the NY Attorney General against dietary supplement companies for non-compliant labeling

• Burdensome Supply Chain Issues
  • Separate labeling for individual states... Prop 65

• Class Action law suits?
  • State law private actions are pre-empted if the State law does not match the Federal law.

• Confused Consumers
  • Dietary Supplements are required to be safe and claims must be substantiated

• Look at what just happened in Arizona!
Tip of the Day on State Laws and Regulations:

• Don’t put your head in the sand!
Take-away:
In addition to general legal considerations, pay extra attention to regulatory issues especially in sports nutrition … and you’ll save time and money!
Thank you!

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