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SARMS – THE FINAL COUNTDOWN

by Jay Manfre

Consumers demand the most powerful and effective supplements to increase strength, energy, and performance. After ephedra was banned, companies searched for the next best stimulant product, and eventually DMAA (1,3-dimethylanamine) flooded the market. When anabolic steroids were officially listed as schedule III-controlled substances, chemists began formulating chemical compounds that would not “violate” the law. So began the “prohormone era” of the supplement world. Prohormones were marketed and sold as dietary supplements up until 2014 when President Obama signed the Designer Anabolic Steroid Control Act (DASCA). Although prohormones are illegal under DASCA, it has not stopped the search for comparable alternatives.

Enter SARMS - Selective Androgen Receptor Modulators. Although SARMS are often referred to as “new,” they were discovered approximately twenty years ago. SARMS are non-steroidal compounds that selectively bind to androgen receptors in specific sites, such as skeletal muscle and bone. They have the ability to be more anabolic as opposed to more androgenic. This offers the potential for increased muscle growth while reducing the likelihood of undesirable side effects that can be caused by steroids – acne, prostate enlargement, hair growth in women, etc. Although there are many different SARMS being investigated by pharmaceutical companies, Ostarine®, a.k.a. MK-2866 and GTx-024, is the most well-known. It is currently being investigated by the pharmaceutical company GTx, Inc. as a treatment for women with Stress Urinary Incontinence.

It didn't take long for athletes and bodybuilders to begin using SARMS to build muscle and enhance performance. In 2008, the World Anti-Doping Agency (WADA) banned SARMS. Although banned by WADA, companies began selling SARMS as “Dietary Supplements.” It is likely that dietary supplement companies saw SARMS as a potential “legal” way to fill the void left in the market after prohormones were banned. DASCA criminalizes the manufacture, sale, and possession of steroids and derivatives and slight variations on compounds that are listed. From a chemical standpoint SARMS are non-steroidal and they are not a derivative or variation of that structure. However, the Food and Drug Administration has publicly stated that SARMS are not dietary supplements.

The Dietary Supplement Health and Education Act (DSHEA) defines a

dietary supplement as “a vitamin; a mineral; an 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 [thereof].” SARMS are not a vitamin, mineral, herb or other botanical, or amino acid. They are synthetic chemical compounds not found in nature or food. It is also not likely that SARMS are a “dietary substance for use by man to supplement the diet by increasing the total dietary intake.”



Although SARMS do not fit the above definitions DSHEA also states that dietary supplements do not include “an article authorized for investigation as a new drug... for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food...” Some SARMS are being investigated as new drugs by pharmaceutical companies and are currently undergoing clinical investigations that have been made public. FDA has pointed to this fact in several warning letters sent to companies

that sell, or sold, SARMS as dietary supplements. FDA also states that SARMS are “prescription drugs” because they are not safe for use except under the supervision of a licensed practitioner.

Although FDA has opined that SARMS are not dietary supplements, SARMS are still being sold as “research chemicals” over the Internet. Whether or not the DEA will be able to effectively police this area of distribution remains to be seen. However, it is quite clear, if you are going to sell SARMS as an ingredient in -- or as -- a dietary supplement, expect a warning letter and possible legal action from FDA.

ⁱ <https://www.govtrack.us/congress/bills/113/hr4771/text>

ⁱⁱ Dalton, J; “Discovery of Nonsteroidal Androgens”; *Biochemical and Biophysical Research Communications*; Volume 244, Issue 1, 6 March 1998, Pages 1–4; Retrieved from <http://www.sciencedirect.com/science/article/pii/S0006291X98982092>

ⁱⁱⁱ <http://www.gtxinc.com/pipeline/>

^{iv} https://www.wada-ama.org/sites/default/files/prohibited_list_2018_en.pdf

^v <http://www.steroidlaw.com/2014/12/designer-anaboloic-steroid-control-act-signed-by-president-obama/>

^{vi} <https://www.britannica.com/science/steroid>

^{vii} https://ods.od.nih.gov/About/DSHEA_Wording.aspx

^{viii} https://ods.od.nih.gov/About/DSHEA_Wording.aspx

^{ix} <http://phx.corporate-ir.net/phoenix.zhtml?c=148196&p=irol-newsArticle&ID=2300266>

^x <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm582464.htm>

WHAT SERVICES DOES CGMB OFFER?

In the ever-changing landscape of the health, fitness and nutrition industries, you need to stay ahead of the curve. Could you survive an investigation of your products, your labels, or your advertising copy? How do you navigate the maze of new regulations ... and run your business at the same time? With FDA policies actively evolving, how can you bring a New Dietary Ingredient to market in compliance with DSHEA? How can you ensure your advertising complies with FTC regulations? What must you do in order to comply with the dietary supplement cGMPs?

Collins Gann McCloskey & Barry PLLC (CGMB), is a law firm dedicated to helping clients in the health, fitness and nutrition communities. With recognized experts in sports performance supplements and regulatory, advertising and marketing law, CGMB offers a powerful bi-coastal team providing a variety of legal services to a whole range of companies from start-ups to established organizations. CGMB offers in-depth experience and personalized attention you can trust to get you the answers you need ... when you need them. The partners of CGMB have been formally rated by the professional legal community as practicing at the highest levels of skill and ethical integrity (AV-rated in Martindale-Hubbell). CGMB can help you stay ahead of the curve.

- Are all your product names and intellectual property protected?
- Have your product labels been reviewed by legal counsel?
- Do you have proper licensing and manufacturing agreements in place?
- Are you covered by adequate indemnification agreements?
- Are all your ingredients DSHEA-compliant?
- How can you bring a New Dietary Ingredient to market or obtain GRAS status?
- Do you have SOPs for recording and reporting Serious Adverse Events?
- How can you substantiate your claims to satisfy FDA, FTC, and other federal and state regulatory agencies?
- Do you have proper insurance coverage and SOPs for customer complaints?
- Have you received a Civil Investigative Demand from the FTC?
- Have you been served with a Class Action suit? How would you handle one?
- Could you survive a 483 inspection?
- Could you survive an investigation of your facility, products, labels or claims?
- Are you fully compliant with cGMPs?

*The best time to ensure compliance with the law is up-front, before there's a problem!
Feel free to call us at (516) 294-0300*

CGMB - SELECTED FIRM PROFILES



Rick Collins, Esq., is based in New York and provides advice to some of the top names in the sports nutrition industry, and is the legal advisor to the International Society of Sports Nutrition and the International Federation of BodyBuilders. He has defended dietary supplement and sports nutrition companies against claims of distribution of misbranded or adulterated products and against serious criminal investigations by FDA and DEA. He is admitted to practice in the courts of New York, Massachusetts, Pennsylvania, Texas and the District of Columbia, and in numerous federal courts.



Alan Feldstein, Esq., an attorney based in Los Angeles and admitted to practice in California, serves Of Counsel to CGMB. He is responsible for advising some of the firm's biggest clients in the sports nutrition industry and has extensive experience with contracts, copyright and trademarks, label and advertising review, supplement fact panel review, claims substantiation and assorted regulatory issues. He brings with him more than a dozen years of advertising and marketing law experience and continues to serve on the adjunct faculty of Southwestern University School of Law.



Jonathan Manfre, Esq. (Jay), is an associate attorney at Collins Gann McCloskey & Barry PLLC. He graduated from New York Law School in June 2015. Jay has been weight training for over twelve years, has competed in two bodybuilding competitions, and has been a consumer of dietary supplements since the age of 18. He is extremely familiar with the regulations of the dietary supplements/sports nutrition industry and very knowledgeable when it comes to effects and function of these supplements.

For more information about CGMB, industry news and updates visit www.supplementcounsel.com.

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