Recommendations to Increase Consumer Protections from Adulterated Nutritional Supplements

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Summary

The proliferation of consumer products in the marketplace today, especially imports, and the resultant recalls and negative public health impacts, has placed a heavy burden on the regulatory agencies charged with protecting consumers. In response, Congress has proposed or passed new laws to increase protections, and place more stringent requirements on products such as food, toys and other consumer products. However, a chronic lack of regulatory resources makes it difficult to inspect and monitor the flood of new products being marketed every day. Testing and certification of high risk nutritional products, such as those at risk for containing steroids and stimulants, should be considered a possible solution to this growing public health issue, including supplementing FDA resources through the use of qualified third party testing and certification laboratories.

Background

The dietary supplement and nutritional products industries have been adversely affected by companies that cannot or will not comply with established U.S. regulations. Regular news reports reveal that consumers are being placed at risk by the use of adulterated or mislabeled products. Laws and regulations written in the early 1990's to address dietary supplements did not anticipate the impact of internet marketing, nor did those laws consider the creativity of chemists synthesizing illegal steroids. The sheer volume of products in this category makes effective enforcement difficult, if not impossible. The proliferation of domestic and imported products, the internet marketing channel, and the demand for performance enhancing drugs, and misleading labels and claims have resulted in many dangerous sport and nutritional supplements being consumed by young and old alike.

Addressing this problem may require legislators and regulators to consider additional protections such as those developed recently for food safety. In 2007, the FDA published the Food Protection Plan, in response to the flood of contaminated or adulterated imported and domestic foods. In it, the use of third party inspection and testing programs is cited as a

possible tool to help close the resource gap. This summer, the House of Representatives passed the Food Safety Enhancement Act (H.R. 2749) to amend the Food, Drug and Cosmetic Act. This bill contains several major improvements to food safety systems. The companion U.S. Senate bill (S.510) under review by the HELP Committee also recognizes testing and certification to help improve consumer food safety. The FDA has already decided to utilize third party certification as part of its strategy to shift from being reactive to proactive in addressing food borne illness or food adulteration issues. Testing and certification of potentially adulterated or mislabeled sports and nutritional products directly supports "Prevention", the first pillar of the 2007 FDA Food Protection Plan.

Recognizing the public's concern about the use of supplements in competitive sports, but also in an effort to protect the health and safety of athletes, major league sports organizations have turned to independent testing and certification as a way to not just to protect the integrity of sport, but to also protect the heath and safety of athletes. Organizations such as the NFL, MLB, PGA, LPGA, and the Canadian Center for Ethics in Sport (CCES) have all embraced NSF International's comprehensive product certification programs for the nutritional supplements they provide to their athletes. Products achieving the certification are inspected more frequently, tested on a lot-by-lot basis, and screened for more than 140 banned substances that are specified by WADA, NFL, MLB, NCAA and a comprehensive list known as NSF Annex A.

Companies that participate in NSF's accredited certification programs are typically well established, reputable companies that want to demonstrate a high level of product safety and regulatory compliance. Companies that manufacture adulterated or mislabeled products generally do not engage in accredited product certification programs. FDA has recently increased its enforcement of violators that openly market steroid containing products. However, there are many websites, manufacturers and raw material suppliers – many from outside of the United States – that develop new steroid analogues every day. Short of mandating accredited product certification for all products in the high risk sports and nutrition supplement category, the Congress and regulators have several options available to help identify, reduce or eliminate dangerous products from the marketplace.

Recommendations

1. The Congress and FDA should explore adoption of some of the food safety provisions of H.R. 2749 amendments to the FD&C Act, including annual facility registration with FDA, establishment of a program for accreditation of laboratories that perform analytical testing for these products, and providing FDA with recall authority over products determined to be mislabeled, misbranded or adulterated.
2. The Congress and FDA should explore how to better enforce the NDI requirements of DSHEA, and explore removing products that have not submitted an NDI that are currently on the market.
3. FDA should explore requiring all chemical ingredients to be labeled in accordance with International Union of Pure and Applied Chemistry (IUPAC) nomenclature/naming guidelines, so that consumers can identify the exact chemical, instead of a proprietary or brand name, eliminating any ambiguity or confusion.
4. FDA should explore increasing its oversight of high risk companies, products, sources, and distribution channels and consider implementing mandatory testing or certification of suspect products.
5. FTC should consider increasing its oversight of product label and marketing claims, and more closely scrutinize products that are marketed to act like a steroid or named similar to a steroid.
6. FDA should explore launching a significant consumer outreach program to educate consumers, parents, teachers, coaches, athletes and the media, on the risks associated with some of these products.

Attachment 1

About the U.S. National Standard for Dietary Supplements

In the U.S., the official private sector administrator of American National Standards is the American National Standards Institute (ANSI). ANSI provides guidelines for, and monitors the systems used to develop, consensus national standards that allow input from all stakeholders so that the resultant standards are usable by all. Thousands of ANSI standards exist that are relied on routinely by regulatory, industry and user groups. The U.S. National Technology Transfer and Advancement Act, as well as OMB Circular A119, encourage government agencies to support the development and use of consensus standards. Indeed, federal agencies routinely participate in the development of consensus national standards, including those developed by NSF International. Manufacturers participate in the development of consensus national standards because it greatly simplifies product compliance. And product users such as consumers, buyers and retailers participate because they rely on certification to these standards as a way to ensure that laws, regulations, and other agreed upon criteria are being adhered to. American National Standards are reviewed regularly to ensure they continue to comply with all relevant criteria, including laws and government regulations. An important feature of NSF International's standards development process is that it requires review by an independent regulatory / academic council of public health professionals. This final review body, the Council of Public Health Consultants, is free of industry participation and votes strictly on a public health basis.

NSF developed the national standard for Dietary Supplements (NSF/ANSI Standard 173) with participation of a balanced stakeholder group, including FDA, NIH, other federal agencies, state regulatory agencies, foreign regulatory agencies, manufacturers, product retailers, industry trade associations and consumer groups. NSF/ANSI 173 references all of the 21 CFR requirements for supplements, including label accuracy for contents, product hygiene (no contaminants or adulterants), product disintegration, product security and as well as facility GMPs and AERs.

Attachment 2

About Third Party Certification

The value of third-party certification to all stakeholders has been demonstrated extensively in fields such as plumbing, electrical, fire-safety, and water treatment chemicals and devices. Millions of products in the marketplace undergo independent product testing and certification every year to satisfy a wide variety of voluntary and mandatory requirements, especially in the areas of public health and safety. These voluntary, third-party programs set a high standard for industry participants to meet, and as such, raise the performance of the entire industry. Certification involves a comprehensive formulation and label review, on-site audit, testing and certification – a process that leads to a binding legal contract. Certified product manufacturers agree to abide by the certification policies that govern the responsibilities of the certified and certifier alike. Certification policies typically allow for public notice and product recall in the event of non-compliance. This enforcement mechanism is not always available to regulators, and as such, is an additional tool available to help them carry out their public health protection mandates. Certified products typically carry the certifier's Mark on their label to facilitate consumer education and choice.

Many companies have taken advantage of the voluntary NSF Dietary Supplement certification program based on NSF/ANSI Standard 173. This standard is also the foundation of the more stringent NSF Athletic Banned Substances certification program, which assures supplements are also drug, steroid, and stimulant free. The comprehensive nature of this program has attracted partnership agreements with professional sports organizations, including NFL, MLB, PGA, LPGA, and the Canadian Center for Ethics in Sport (CCES). Products achieving this higher level of certification are inspected more frequently, on a lot-by-lot basis, and screened for more than 140 banned substances, and depending on the program, the list of prohibited substances specified by WADA, NFL, MLB, NCAA or NSF Annex A.

Attachment 3

About NSF International

NSF International, an independent, not-for-profit, non-governmental organization, provides national standards development, product testing and certification, education, and related services in public health and safety. Focusing on food, water, dietary supplements and the environment, NSF International develops national consensus standards under the auspices of the American National Standards Institute (ANSI), offers voluntary, ANSI-accredited, third-party conformity assessment services, and provides learning opportunities through its Center for Public Health Education. The primary stakeholder groups involved in consensus standards development include regulators, user groups, and industry representatives, as well as the general public.

Founded at the University of Michigan, School of Public Health in 1944, NSF is recognized worldwide for its scientific and technical expertise in the public health and environmental health sciences. NSF employs more than 800 professional staff including engineers, chemists, toxicologists, microbiologists, food safety professionals, water quality experts and environmental health professionals with broad experience both in public and private organizations.

NSF works closely with federal and state agencies involved in food safety and water quality, including EPA, FDA, USDA, CDC and others. NSF is also a Collaborating Centre of the World Health Organization (WHO) for Food Safety, Water Quality and Indoor Environments.

NSF inspects production facilities in more than 80 countries. It maintains its 75,000 square foot headquarters and 150,000 square foot laboratory facility in Ann Arbor, Michigan. The NSF certification mark is recognized around the world and is respected by regulatory agencies at the local, state, and federal levels. Laboratories are ISO Guide 17025 compliant and Certification Programs are ANSI accredited.