News Release

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AlphaSize® Alpha-GPC Vs. Generic, Fully Synthetic, A-GPC

Austin, TX – The success of AlphaSize® Alpha-Glyceryl Phosphoryl Choline (Alpha-GPC; A-GPC) the past nearly 20 years in the dietary supplement, food, and beverage arenas, has enticed other companies to offer an alternative, “generic”, fully synthetic, A-GPC to the marketplace. This A-GPC is produced via synthetic chemistry, using vastly different, unnatural, starting raw materials and using vastly different production schemes. So is this generic, fully synthetic A-GPC the same as AlphaSize® A-GPC? The short answer is no, it is not the same.

Proof of purity, history of safe use, FDA regulatory compliance, and research validation are critical requirements these days, and for good reason. This exists abundantly for AlphaSize® A-GPC, as it is safe, legal, full FDA GRAS, 100% natural (not synthetic), water soluble, tasteless, odorless, extremely stable and nonreactive, IGEN™ Non-GMO Certified. This is why AlphaSize® A-GPC is widely used in dietary supplements, sports nutrition and healthy aging finished products, in beverages shots, bars, chewing gum, gummies, and in conventional foods and pet supplements.

Generic, fully synthetic, A-GPC may in fact be manufactured using genotoxic (chemical toxins that damage genes) and/or endotoxic (toxins form bacteria that cause disease) impurities present in the starting raw materials, which can also be present in the finished ingredients. In contrast, AlphaSize® A-GPC is 100% natural, and no synthetic chemicals that might contain impurities are used in its manufacture. In addition, AlphaSize® A-GPC is the only A-GPC ingredient whose GRAS dossier, related to safety, was submitted in its entirety to FDA for review. And in addition, it has been evaluated in a multitude of published human studies, demonstrated to providing a variety of profound mental and physical performance benefits, as well as in its complete safety profile.

Through intensive testing, we have identified generic, fully synthetic, A-GPC ingredients with impurities and non-bioavailable components, and the sellers of this material have been known to provide Chemi Nutra’s regulatory documentation, not their own, for these adulterated A-GPC ingredients. In fact, these generic, fully synthetic A-GPC ingredients are not supported by sufficient safety data or by FDA’s review, and it is not legal per existing FDA regulations. Therefore, generic, fully synthetic A-GPC is unfit for consumption, and knowingly distributing and using this adulterated material is not only unethical, but it poses a liability risk to the manufacturers and to the health of end user customers. In the end, these practices severely undermine the credibility of our industry.

One path to proven safety requires evidence, reviewed by FDA acting as the ultimate authority, that ingredients are safe for human consumption. The Dietary Health and Education Act (DSHEA; 1994) requires every manufacturer of an ingredient introduced after 1994 to file for New Dietary Ingredient (NDI) acceptance with FDA, which maintains a listing of all NDI notifications and who explicitly states:

1. “The listing of a new dietary ingredient in this table does not mean that another manufacturer can lawfully market the dietary ingredient in a dietary supplement. Each manufacturer is responsible for ensuring compliance with the Act.”
2. “Importantly, if a product containing a new dietary ingredient is marketed without the required notification, unless exempt, the product may be adulterated as a matter of law.

A second path to proven safety is the GRAS (Generally Recognized As Safe) process, and under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act, any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive.

“Nearly 20 years ago, Chemi Nutra introduced our branded, high quality, AlphaSize® A-GPC, “The Original A-GPC”, to the supplement, food, and beverage industries. It is proven safe and legal for use, unlike generic, fully synthetic, A-GPC, and it is patented and produced in our own facility in Italy, where any customer can audit its production and see firsthand our extreme attention to quality control. Our all-natural, branded, AlphaSize® A-GPC is used in thousands of finished products – nutritional supplements, sports supplements, gummies, RTDs, beverages, and shots. Consumers look for the AlphaSize® A-GPC logo on finished product labels, as their assurance of highest quality, safety, and validated health benefits. We have sponsored numerous published studies on our branded A-GPC, demonstrating its impressive mental performance and physical performance benefits”, stated Scott Hagerman, president of Chemi Nutra.

“Chemi Nutra is now taking legal and regulatory actions, represented by the prominent law firm, Rivkin Radler LLP, and we will be taking additional wider ranging actions in the very near future. Without doubt, our AlphaSize® A-GPC is one of the most effective functional ingredients to ever exist, and our customers tell us they want 100% safe, research supported A-GPC specialty ingredients that are all natural, non-synthetic, and GMO-free”, added Mr. Hagerman.

Chemi Nutra is the U.S. business unit of parent company Chemi S.p.A., a privately held pharmaceutical and nutraceutical company based in Milan, Italy. Chemi, with cGMP certified manufacturing facilities in Italy and Brazil, is best known in the U.S. nutritional arena for its introduction of both phosphatidylserine (PS) and A-GPC.

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