



## **Proprietary blends in dietary supplements protect trade secrets and foster innovation**

A proprietary blend is a unique preparation of ingredients in a dietary supplement that is formulated for a specific purpose. The quantities and ratios of ingredients in the proprietary blend are considered a trade secret, like a special recipe. Some proprietary blends are in fact secret formulas based on folk medicine or traditional herbal preparations. Others are the result of highly scientific research and years of clinical investigation. In either case, the creators of the proprietary blends in dietary supplements have a special interest in protecting the confidential nature of the formula—for the same reasons that the formulas for Coke and Pepsi, or A-1 steak sauce, are all closely-guarded company secrets.

When Congress enacted the Dietary Supplement Health and Education Act of 1994 (DSHEA), it expressly created a unique labeling situation for proprietary blends in dietary supplements to protect their confidential formulas. While the law generally requires “the listing of dietary ingredients shall include the quantity of each such ingredient per serving,” (21 U.S. Code § 343(q)(5)(F)(ii)), it allows the label of a proprietary blend to simply provide the total quantity of the blend per serving—not the amounts of each ingredient. The statute and the attendant regulations (see 21 CFR 101.36) both make clear that the label must disclose the identity of all ingredients in the blend, just not their individual amounts, and the ingredients “shall be declared in descending order of predominance by weight...”

Both small and large companies use the labeling of proprietary blends to protect their intellectual property. Having to disclose the exact formulas would allow competitors, store brands and even counterfeiters to make exact copies and undercut their products with lower-quality copycats or with cheap knockoffs. While reverse engineering is possible, it’s expensive and time-consuming, so the ability to keep one’s formula a secret still has merit. Having the proprietary blend labeling requirement preserves brand quality and ensures supplement users get the same blend that they know and trust every time.

Some industry critics have suggested that proprietary blends are dangerous or a “loophole” in the law. Both allegations are incorrect. FDA can obtain the exact ingredient mixture in proprietary blends when it conducts routine inspections of facilities under the GMP regulations, so these recipes cannot hide risky ingredients that would be unsafe for human consumption. Because the label must identify the identity of the ingredients, and FDA has access to the quantities when it asks for them, consumers can be assured their products are safe. What sets dietary supplements apart is that, unlike conventional food and beverages, supplements must disclose on the label the exact ingredients in their proprietary formulations. And supplement brands that contain a proprietary blend are still subject to all other regulations and requirements imposed by FDA, including inspections, adherence to Good Manufacturing Practices (GMPs), serious adverse event reporting and complying with all other labeling requirements.

The proprietary blend “exception” was an intentionally and carefully crafted provision to provide a minimal level of intellectual property protection for supplements to create incentives for innovation. CRN values this aspect of the 1994 law and strongly advocates to protect the proprietary blend provision of DSHEA.