

STEVIA WONDER – THE SWEET HERB WITH A FUTURE?

By Scott C. Tips, General Counsel, NHF

Winston Churchill once said, "Success is the ability to go from failure to failure without losing your enthusiasm." He would know since his life had many failures but was also most known for spectacular success. Yet, nothing epitomizes this expression more than the regulatory experience of stevia. Stevia is a natural sweetener that not only does not trigger the usual insulin release that other sweeteners do, but actually *helps* diabetics (1, 2). It is an incredible substance.

And, incredibly, for decades, it could not be sold in the United States as a sweetener, thanks to the U.S. Food and Drug Administration (FDA). The FDA deemed it not proven safe and banned its import – this from an agency that saw fit to approve for sale into the marketplace such marvels of safety as aspartame, Vytorin, Vioxx, Trasyolol, Avandia and Zetia, let alone those killer antidepressants that have been at the root of a plague of school shootings by little more than children. Many thousands of needless deaths have resulted from FDA's thoughtless actions, all the while natural, healthful products such as stevia have languished in a regulatory limbo rather closer to hell than to heaven.

Pioneers in the sale of stevia – such as Sunrider International – suffered from FDA raids, legal actions and outright seizures of its stevia-based products until the Dietary Supplement Health and Education Act of 1994 (DSHEA) was passed, and the company could file a letter with the FDA asking the Agency to either recognize stevia's grandfather status or else approve it as a New Dietary Ingredient. Refusing the former, but succumbing to DSHEA's mandates, the FDA at last recognized that stevia could be sold as a dietary supplement only and not a sweetener. The year was 1995.

Yet, as recently as last fall 2007, the FDA was still sending warning letters about the use of stevia in foods. Hain Celestial Group was on the butt end of one such letter, with the FDA demanding that the company relabel its Celestial Zingers To Go tea and drink mixes, which contain stevia and hence were "adulterated." The company quickly complied.

Sweet Fortune

This year, and after decades of near exclusion from the American mass market, stevia's recent support from some heavy-hitters paid off. Perhaps realizing that aspartame and sucralose are not rising high on the hit-parade list of knowledgeable consumers, some corporate giants have been casting around for a possible substitute.

Shunned by some governments for a time (and still) because of tests that supposedly showed mutagenic activity and possible liver toxicity, stevia actually has a good track record when it comes to safety. In 2006, the World Health Organization (WHO) performed a complete and thorough analysis of then-recent experimental studies of stevioside and steviolol derived from stevia and concluded that "stevioside and rebaudioside A are not genotoxic *in vitro* or *in vivo* and that the genotoxicity of steviol and some of its oxidative derivatives *in vitro* is not expressed *in vivo*." Many other reviews and studies have shown stevia not only to be safe and beneficial for diabetics, as noted above, but to reduce hypertension and reverse metabolic syndrome, all while having 30-45 times the sweetness of sucrose.

In addition, at the Codex level, in the Codex Committee for Food Additives, I have noticed that steviol glycosides have steadily advanced in the food-additive approval process there, particularly at the behest of the Paraguayan delegation. If this unopposed trend continues, as I believe it will, then the ingredient will in a few short years become an approved food additive ingredient per Codex standards. All Codex signatory countries will then be beholden to permit international trade in steviol glycosides.

So, seeing the potential, the Coca-Cola Company and Cargill joined forces to find a way to introduce their version of stevia into the food and beverage marketplace. Starting last year, the two companies began in earnest to push for the regulatory acceptance in the United States of stevia as a food additive and not just as a dietary supplement, even though research had been conducted on the ingredient for many years prior. Coca-Cola alone has

filed 24 patent applications for its stevia ingredient, and already uses its stevia derivative as a sweetener in Japan where it is a legal food additive. If successful here in the United States, the companies know that their alternative-sweetener market could be huge, a market some have valued at almost \$1 billion.

A Food Additive, not Dietary Supplement

Cleverly but not unusually, the Coca-Cola/Cargill approach – as well as that taken independently by Whole Earth Sweetener Company in conjunction with PepsiCo – was to seek Generally Recognized As Safe (GRAS) status for their versions of stevia through “self-determination.” This method – as opposed to the other approach where a company petitions the FDA for GRAS food-additive status – lets company experts determine ingredient safety with significant, published, peer-reviewed studies, subject to FDA acceptance. Of course, Coca-Cola/Cargill and Whole Earth Sweetener made sure to retain enough stevia experts with sufficient agency contacts and experience who could ensure that the FDA would give their versions of stevia the most deference in achieving GRAS status.

To that end, the two groups – joined by Wisdom Natural Brands, a real stevia pioneer – just recently announced the introduction of their branded stevia-derived sweeteners, “Truvia,” “PureVia,” and “Sweet Leaf,” made from rebiana in the first two instances and steviol glycosides in the last. Cargill and Whole Earth Sweetener informed the FDA of their determinations that the use of the stevia-derived substances is GRAS. (The GRAS notices are available on FDA’s Web site at <http://www.cfsan.fda.gov/~rdb/opagn08.html>.) Wisdom Natural Brands, on the other hand, has simply stated that Sweet Leaf is self-affirmed GRAS without any FDA notification. The FDA has not yet stated whether it has accepted the self-determined GRAS status, but the companies have lined up impressive scientific evidence in support of their notices.


For example, Cargill-funded research, published electronically in the peer-reviewed scientific journal, *Food and Chemical Toxicology*, showed that rebiana is safe for use in foods and beverages. But, remember, rebiana is not the same as stevia. They both come from the leaves of the stevia plant, but rebiana is a highly-purified extract that Cargill seeks to solely own and market.

Hence, the Dilemma

Whole-food purists, such as many NHF members, have long contended that, to eat wisely, the whole plant should be consumed and not just components of the plant

drawn from it. In the case of stevia, some even argue that only the green or brown stevia is healthy to use since the purified, refined white extracts or powders lack important phytochemicals. Others counter that it does not matter, especially where the alternative is the far-worse sucrose and high-fructose corn syrup, not to mention artificial sweeteners such as aspartame.

Can we think, then, that success – at long last – might be at hand for stevia? Or is this just another example of big companies trying to corner the market on yet another natural product that should be freely sold? The answer might lie with how Coca-Cola, Cargill, Whole Earth Sweetener Company, PepsiCo, and Wisdom treat their stevia competitors in the future. If history is any example, we might have much to be concerned about.

Should GRAS notification be accepted by the FDA, then this may not necessarily be good news for stevia in general as these companies will almost certainly complain to the FDA about the use of stevia by other companies in conventional food products. Should that happen and the government act to stifle other companies’ sales of stevia, then the stevia “success” story may well be a still-born one, as yet another corporate giant uses government powers of coercion to corner a piece of the market – this time the stevia market. 

References

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