

A Response to Attacks  
ON THE SECOND EDITION OF THE  
*Comparative Guide*  
*to Nutritional Supplements*



**Y**ears ago, Melaleuca wrote a critique of the second edition of the *Comparative Guide to Nutritional Supplements*. More than four years after the guide went out of print, this diatribe continues to be circulated.

The objective of this paper is to clarify a few key points.

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In 2002, Melaleuca, a manufacturer of dietary supplements, disseminated through its distributorship and posted on its website a critique of the *Comparative Guide to Nutritional Supplements* (2<sup>nd</sup> edition). That edition of the guide went out of print in the fall of 2002 with the launch of the third edition of the *Comparative Guide*.

The third edition of the *Comparative Guide*, itself now long in the tooth after almost four years in print, was significantly enhanced, based on input from the public, from sources within the dietary supplement industry—including Melaleuca—and from evolving scientific evidence. Nevertheless, Melaleuca persists in disseminating their critique, written to address perceived deficiencies in the second edition of the *Comparative Guide*, to attack the third edition of our guide—with the full knowledge that their concerns have no currency.

NutriSearch Corporation now owns the copyright to the *Comparative Guide to Nutritional Supplements*. The fourth edition, scheduled for release in February of 2007, will further enhance our comparisons, again based on feedback from the industry, from consumers, and from recent scientific findings.

We have always welcomed constructive criticism of our analytical model, and, where appropriate, will seriously consider such criticism when modifying and improving our analysis for future editions of our work. On that note, while we thank Melaleuca for taking the time to critique our work, we believe that some of this company's public remarks go well beyond fair comment. Misrepresentations of the facts and personal attacks on the guide's principal author, Lyle MacWilliam, have no place in objective criticism. Indeed, some of the comments in the Melaleuca document indicate that the anonymous authors of the critique either did not read the *Comparative Guide to Nutritional Supplements* in full or that they failed to understand what they were reading.

## ***GMP compliance***

**Melaleuca claims:** “MacWilliam begins by attacking the quality control processes of supplement producers.”

**Fact:** What was printed in the 2<sup>nd</sup> edition of the guide—and what both MacWilliam and NutriSearch Corporation continue to stress—is that nutritional supplements should be manufactured to **pharmaceutical-model** GMP, rather than to the **food-model** GMP that most U.S. supplement manufacturers use.<sup>1</sup>

- Compliance with pharmaceutical-model GMP gives consumers assurance that the supplements they consume meet stringent pharmaceutical standards for content, potency, and dissolution, and do not contain unwanted impurities.
- While food-model GMP provide some protection for consumers, they do not require manufacturers to follow tough and sometimes costly procedures, such as the quarantining and testing of each ingredient for purity, potency, and identity when it arrives at their facility.
- Discussions of GMP compliance and the differences between food-model GMP and pharmaceutical GMP can be found on **pages 23-25** and **24-26** in the 2nd and 3rd editions, respectively, of the *Comparative Guide to Nutritional Supplements*. This issue is also addressed in the Product Quality Checklist, found on **page 24** of the 2nd edition and **page 26** of the 3rd edition.

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1 MacWilliam LD. *Comparative Guide to Nutritional Supplements*. 2nd ed. Vernon: Northern Dimensions Publishing; 2001.

Our efforts to find information on the GMP that Melaleuca claims to follow have been frustrating. A 2006 search of the Melaleuca website and an online Google search reveal a single document alluding to quality standards.<sup>2</sup> This document talks about the company's use of natural products, but **makes no mention of GMP compliance**. It also mentions Melaleuca's Quality Assurance lab, but does not indicate whether this lab is "in-house" or an outside agent, or whether it meets quality and calibration standards set out by the International Standards Organization for laboratory procedures (ISO 17025).

Most companies that meet national or international standards prominently display their certifications. Melaleuca's silence on GMP compliance and quality standards, combined with the outsourcing of the manufacture of their dietary supplements, raises concern regarding their ability to assure finished product quality.

*NutriSearch Corporation and MacWilliam consistently state that manufacturing dietary supplements to food-model GMP does not adequately protect consumers. We recommend that consumers look to products that are manufactured "in-house" by companies that can demonstrate compliance with pharmaceutical-model GMP and, ideally, participate in a third-party certification program, such as the United States Pharmacopeia Dietary Supplement Verification Program or the NSF Dietary Supplement Certification Program.*

## Safety

**Melaleuca Claims:** "MacWilliam goes on to attack the quality, purity and composition of all supplements ... to back up his argument he has to go back to the beginning of the last century."

**Fact:** Many U.S. studies have shown discrepancies between what is on the label and what is in the bottle. The study alluded to by Melaleuca, conducted in 1991, includes data from as far back as 1908.<sup>3</sup> Moreover,

- Case law dating back to the 1930s shows that the FDA, the U.S. regulatory watchdog for food and drug safety, has long been battling unscrupulous manufacturers of nutritional products who pose concerns for public safety because the consumer could not be assured that what was on the product label was actually in the bottle.
- The FDA has recently identified several products in the U.S. market that are not accurately labelled or that contain potentially harmful contaminants. The agency has cited the following examples of safety violations:
  - o The use of non-food-grade chemicals in the manufacture of dietary supplements;
  - o Product contamination with excessive amounts of lead;
  - o Sub-optimal levels of nutritional components as claimed on the label (one product had only 35 percent of the amount of folic acid claimed on the label);
  - o Products exceeding safe upper levels of nutrients (one manufacturer recalled a niacin product after it received reports of nausea, vomiting, liver damage and heart attack associated with the use of its product).

**Consumerlab.com, a U.S.-based testing facility for dietary supplements, recently completed a study of 47 nutritional supplements and found that eleven U.S. multivitamin products—almost 25% of the products tested—failed their quality control tests.** A number of the products were significantly short in the amount of important vitamins or minerals. Some contained too much lead and another failed to break apart properly for absorption. To review this report, log on to [www.consumerlab.com](http://www.consumerlab.com).

*Melaleuca may choose to dismiss these violations as not material; however, we believe that the issue of identity, content, and purity is extremely important when it comes to public safety.*

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2 "When is Natural Really Natural?" Melaleuca corporate web site, <http://www.melaleuca.com/wc/index.cfm?m=1&p=159>, Accessed October 27, 2006

3 Awang DVC et al, Echinacea. *Can J Pharmacol* 1991;124:512-516

## ***Nutrient forms***

**Melaleuca claims:** MacWilliam “completely ignores the effect of nutrient forms and absorption rates in his analysis....”

**Fact:** This statement is factually incorrect and completely disregards the section dealing with the creation of the second edition’s Nutrient Profile Score (**Chapter 4**, *Comparative Guide to Nutritional Supplements*, 2<sup>nd</sup> edition).

- The twelve rating criteria used to evaluate products for the 2<sup>nd</sup> edition are discussed in detail on **pages 32-34** of the guide.
- Two of the twelve criteria, “Bioactivity of Vitamin E” and “Bioavailability,” deal *specifically* with nutrient forms, including the active form of vitamin E and mineral forms, respectively.
- Melaleuca clearly agrees, based on their arguments, that nutrient forms are a critical component in allowing a product to score highly against the *Blended Standard*.

The scientific rationale for our expanded and improved third edition criteria are discussed in detail in **chapters 5 through 16** of the *Comparative Guide to Nutritional Supplements* (3rd edition).

*Melaleuca is advised to read the Comparative Guide to Nutritional Supplements carefully before dismissing its findings.*

## ***Unbiased sources***

**Melaleuca claims:** In the section of the Melaleuca critique titled, “Exactly Who Are These Experts?” Melaleuca contends that the four independent published nutritional authorities, whose recommendations for daily nutritional intake form the basis of the *Blended Standard*, are biased and that their recommendations “slant” the *Blended Standard*.

**Fact:** Each of the four authorities cited have unquestionably excellent credentials and, as the anonymous Melaleuca authors contend, “... are knowledgeable. And all four are capable of providing advice on nutrition.” Even so, Melaleuca invests considerable space and ink trying to discredit them.

- MacWilliam chose independent sources of published nutritional recommendations specifically to avoid any personal bias from seeping into the comparisons.
- Our comparative guides simply report what independent nutritional experts have written and use their published recommendations to compare supplements to that third-party standard.

*Because neither NutriSearch nor author Lyle MacWilliam creates these published recommendations, we cannot influence how supplements compare to the standard designed from them. In the third edition of the Comparative Guide, the number of published authorities used to create the Blended Standard was increased to seven. The fourth edition of the guide, to be released in February, 2007, further expands the number of independently published authorities to twelve.*

## ***Improvements to the analyses***

NutriSearch Corporation continues to improve its comparisons and look for new ways to serve consumers. In the third edition of the *Blended Standard*, released early in 2003, several changes were made to the comparisons and to their presentation in the guide. These changes include the following:

- The 3rd edition of our guide uses a median value for each nutrient, rather than an averaged value. This provides a more accurate assessment of central tendency than the statistical average when dealing with a small sample size (as is the case with our referenced authorities).
- As we became aware of other publications regarding comprehensive recommendations for daily intake, we increased the number of cited authorities to seven from the previous four.
- We discontinued the practice of including the top-rated product as a standard on every page. We concluded that providing the graph of the top-rated product for purposes of comparison on each page may create the impression of bias.
- We significantly enhanced our evaluative criteria, creating a more robust 14-point quantitative scale, and provided the scientific justification for each criterion in a separate, fully-referenced and thoroughly-researched chapter in the guide.

Our upcoming fourth edition includes several additional changes that we are very excited about, based in part on consultation with the public and with nutritional supplement manufacturers. These include, for the first time, independent laboratory verification of product claims for our NutriSearch GOLD Medal of Achievement™ earners. Our comparative guides have always stressed that consumers need to look beyond the label information and verify that their chosen supplements meet quality standards. Our new NutriSearch Medal of Achievement Program™ allows us to provide independent verification of GMP compliance and product label claims.

## ***The author's credentials***

Mr. MacWilliam is a trained biochemist and kinesiologist and a contributing author to leading health publications. He has served, at the behest of Canada's Minister of Health, on an expert advisory team for natural health products, which developed a new regulatory framework to ensure Canadians have access to safe, effective and high quality nutritional products. His wide-ranging consulting experience includes work for the British Columbia Science Council, Environment Canada, Human Resources Development Canada, and Health Canada. He has been invited by companies, organizations and individuals around the world to speak on nutrition and lifestyle issues, including presentations on adults' and children's supplementation needs, the prevention of degenerative disease, and the need for lifestyle change to promote optimal health.

Several leading nutritional manufacturers, including Douglas Laboratories, Cox R&D Laboratories, Source Naturals, TrueStar Health, USANA Health Sciences, and Vitamin Research Products, use our *Comparative Guide to Nutritional Supplements* in highlighting the quality of their products. We have been assured of the confidence with which these respected companies regard our research and analysis and the value that they place on the *Comparative Guide to Nutritional Supplements* as a consumer-based tool to help sort the wheat from the chaff.

Neither the author, Lyle MacWilliam, MacWilliam Communications Inc., nor NutriSearch Corporation have any fiduciary ties to any of the companies or products listed in the *Comparative Guide to Nutritional Supplements* or its sister publications; nor do they profit in any way from the sale of nutritional products listed in the guide. In addition, production of the guide is not funded by any nutritional manufacturer or other public or private interest. It is the sole creative effort of MacWilliam Communications Inc. and NutriSearch Corporation.