

There is no proven relation between Herbalife products and liver disease

We strongly object to the inclusion of Herbalife products in association with liver disease. We have repeatedly refuted the study mentioned. Green tea is an ingredient in Herbalife Concentrate Tea at safe levels found in green tea beverages generally. This tea is a beverage and is not used as a supplement for quick weight loss. Green tea has been safely consumed around the world for thousands of years. The Herbalife green tea is water-extracted, just as green tea would normally be brewed, at Herbalife's facility under careful supervision with extensive quality control using advanced methods of analysis. No known hepatotoxins were ever found in our products, nor was there any conclusive evidence of causality between any of our products and ingredients and liver disease.

In addition to Herbalife's continued efforts to address this issue in the literature¹⁻¹⁰, it should be also be acknowledged that independent medical experts have recently revisited the historical cases involving Herbalife and are questioning the methodology by which these cases were evaluated¹¹. In many instances, these same experts are assigning weaker causality outcomes than were previously determined and certain events also appear to have been more likely associated with pre-existing etiologies amongst these consumers (e.g. viral hepatitis and alcoholism)¹². Additionally, not only were the five cases mentioned in your article deemed extremely mild by the investigating physicians, the cases are significantly outdated and do not represent a reoccurring issue in Iceland. In fact, the article clearly states that the 5 cases were collected during a retrospective review of cases reported to Icelandic hospitals between 1999 and 2008. We have been in contact with the Icelandic investigators and as of 2011, no new Icelandic cases have been received in addition to these 5. Therefore, the information provided in your article regarding Herbalife is actually a regurgitation of old issues that have consistently been refuted. It should also be acknowledged that 5 cases reported over a 16-year duration is more likely due to an idiopathic etiology rather than the use of Herbalife products. The inconsistent presentation types, widely varied durations to onset, and no common product/ingredient being consumed amongst these 5 patients further suggests idiopathic causality. Furthermore, since 2005 in response to the original brand-name association with liver injury, 27 governments around the world have investigated this issue and decided no regulatory action involving Herbalife products was warranted. Herbalife products are a source of healthy nutrition. They are not herbal medicines. They are protein shakes, protein snacks, vitamins and nutritional supplements, energy and fitness drinks, and skin and hair care products. These products are primarily based in vegetable proteins, fish oils, vitamins, and minerals for which safe use is very well established. Some of the company's products also contain botanical ingredients that are well characterized and tested. These botanicals are included in Herbalife products at levels that are in a safe nutritional range. They have antioxidant properties and support normal function, and are labeled in accordance with all the applicable laws.

Many consumers who choose to use Herbalife weight-management products for weight loss are overweight, some significantly so. Pre-existing medical conditions such as obesity and diabetes can be associated with non-alcoholic fatty liver disease, a disorder that may return certain types of abnormal blood test results. These test results, therefore, may have nothing to do with any nutritional supplement, but rather are the result of a pre-existing medical condition. In addition, it is possible for an individual to have an individualized immune reaction to a product, the same way one might have an allergic reaction to any food product; for example, strawberries or shellfish. In consideration for these or other individual susceptibilities, Herbalife supports the recommendation that consumers visiting their doctors for medical treatment inform them of any supplements they may be taking and always take supplements as directed on the label.

In the United States, Herbalife actively lobbied Congress to pass legislation mandating the submission of all dietary supplement and over-the-counter drug serious adverse events to the Food & Drug Administration. That law took effect in December 2007 and mandates all serious adverse event be submitted to the FDA within 15 days. In fact, Herbalife has a well-developed adverse event reporting system that monitors and evaluates the small number of adverse events received globally. In the spirit of product stewardship we remain committed to cooperate openly and fully in the evaluation of any adverse event potentially associated with Herbalife products. All adverse event reports are investigated thoroughly in consultation with

the consumer and the physician (if they are available) to fully understand the facts. None have resulted in the compulsory withdrawal of any product, ever.

I want to assure you that Herbalife products are developed incorporating scientific research findings and produced to levels of quality and safety in compliance with the applicable laws and industry standards. We take product safety very seriously and that is reflected in the way in which we work closely with opinion leaders, regulators and governments around the world. Herbalife is a responsible company that has been in business for over 30 years and sells products through independent distributors in over 85 countries. Consumers can be confident in the safety of our products.

Vasilios H. Frankos, M.S., Ph.D.,
Senior Vice President
Global Product Science, Safety and Compliance

References:

- Appelhans K, Frankos V, Shao A. Misconceptions regarding the association between Herbalife products and liver-related case reports in Spain. *Pharmacoepidemiology and Drug Safety*, 2012;21:333–334. DOI:10.1002/pds.<http://onlinelibrary.wiley.com/doi/10.1002/pds.3203/abstract>
- Appelhans, Kristy; Smith, C; Bejar, E; Henig, YS (2011). "Revisiting acute liver injury associated with herbalife products". *World Journal of Hepatology* 3 (10): 275–7. doi:10.4254/wjh.v3.i10.275. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3208182/>
- Appelhans K, Goldstein L. Revisiting liver injury associated with dietary supplements. *Liver Int* 2011. DOI:10.1111/j.1478-3231.2011.02547.x. <http://onlinelibrary.wiley.com/doi/10.1111/j.1478-3231.2011.02547.x/abstract>
- Appelhans K, Frankos V. Herbal medicine hepatotoxicity revisited. *J Hepatol* 2011. DOI:10.1016/j.jhep.2011.06.01910. <http://www.ncbi.nlm.nih.gov/pubmed/21782760>
- Bejar E, Smith CR, Appelhans K, Henig YS. Correcting a misrepresentation of hypervitaminosis A attributed to Herbalife product consumption. *Exp Mol Pathol* 2011; 90(3):320–321. <http://www.ncbi.nlm.nih.gov/pubmed/21315714>
- Ignarro L, Heber D, Henig YS. Herbalife nutritional products and liver injury revisited. *J Hepatol* 2008. DOI:10.1016/j.jhep.2008.05.005. <http://www.ncbi.nlm.nih.gov/pubmed/18550201>
- K. Appelhans, R. Najeeullah & V. Frankos. Letter: retrospective reviews of liver-related case reports allegedly associated with Herbalife present insufficient and inaccurate data. *Aliment Pharmacol Ther* 2013; 37:73-74. doi:10.1111/apt.12217.<http://onlinelibrary.wiley.com/doi/10.1111/apt.12217/full>
- K Appelhans, R Najeeullah, & V Frankos. Letter: A correction of misinformation regarding Herbalife. *World J Hepatol* 2013 October 27; 5(10): 601-602. doi:10.4254/wjh.v5.i10.601. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3812465/>
- K Appelhans, R Najeeullah, V Frankos & A Shao. Outdated Perspectives Potentially Biased Conclusory Statements Regarding Herbalife Products. *Journal of Applied Pharmaceutical Science* Vol. 4 (02), pp. 133-134, February, 2014. DOI: 10.7324/JAPS.2014.40222. http://www.japsonline.com/admin/php/uploads/1199_pdf.pdf
- K Appelhans, R Najeeullah, & V Frankos. Considerations regarding the alleged association between Herbalife products and cases of hepatotoxicity. *Internal and Emergency Medicine*. January 2014. http://link.springer.com/article/10.1007/s11739-014-1048-9?sa_campaign=email/event/articleAuthor/onlineFirst
- R Teschke, C Frenzel, J Schulze, A Schwarzenboeck, & A Eickhoff. Herbalife hepatotoxicity: Evaluation of cases with positive reexposure tests. *World J Hepatol* 2013 July 27; 5(7): 353-363. doi:10.4254/wjh.v5.i7.353.<http://www.ncbi.nlm.nih.gov/pmc/articl>