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February 9, 2004

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Docket No. 2003N-0496

To Whom it May Concern:

Herbalife International of America, Inc. ("Herbalife") submits these comments to the Food and Drug Administration ("FDA") in response to the November 25, 2003 Food Labeling: Health Claims; Dietary Guidance, Advance Notice of Proposed Rulemaking. 68 Fed. Reg. 66040.

For over 24 years, Herbalife has marketed scientifically formulated conventional food, dietary supplements and personal care products through a network of independent distributors in 58 countries worldwide. Today, as the world's largest weight loss company, Herbalife products are produced by state-of-the-art domestic and international contract manufacturers to our exacting. Herbalife prides itself on formulating innovative, healthful products. Keeping abreast of the latest research, our world-class Scientific and Medical Advisory Board educates consumers about the valuable attributes of these products through appropriate labeling, advertising and training. Clearly, health claim statements are one means by which Herbalife informs consumers.

FDA is requesting comments on how best qualified health claims can be regulated. FDA has identified three proposed options: (1) continue the current interim procedures and evidence-based ranking system established by guidance this past year;<sup>1</sup> (2) mandate full notice-and-comment rulemaking as is required for unqualified health claims; or, (3) treat qualified health claims as outside of the Nutrition Labeling and Education Act (NLEA),

<sup>1</sup> The interim procedures were articulated in two Guidances published this year outlining the process for submitting and evaluating petitions for qualified health claims: "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements," and "Interim Evidence-based Ranking System for Scientific Data." In the second guidance, FDA outlined the process for systematically evaluating and ranking the scientific evidence for proposed qualified health claims. Specifically, FDA stated it will review the body of evidence for: (1) quantity (*i.e.*, the quantity of studies, number of individuals studied and generalizability of the findings); (2) consistency (*i.e.*, sufficient number of well-designed studies with consistent results and among studies that are less well designed); and, (3) relevance to disease risk reduction in the general population or targetted subgroup.

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which provided for health claims for foods, and enforce against them in the post-market environment pursuant to general false and misleading standards. With all due respect, Herbalife believes that there is a fourth option worthy of consideration by the Agency.

First, in considering FDA's proposals, Herbalife agrees with FDA that Option 2 will be too restrictive and time consuming. It provides no incentive for companies meaningfully to pursue health claims, as companies know how difficult it is to obtain a final health claim rule through notice-and-comment rulemaking. In addition, it does not provide the flexibility necessary to modify claims in an efficient or timely manner as science evolves. In this field of rapidly advancing science, practicable solutions are called for. Additionally, Option 2 effectively will chill a company's First Amendment right to make appropriately qualified health claims.

Option 3 will aid neither industry nor FDA as it seeks to achieve a workable solution to health claims. No guidelines would be provided, and, therefore, industry would have no clear understanding of when science might suffice. In addition, distributors such as Herbalife would have no guarantee that the products they are developing could be marketed as contemplated. An unregulated environment benefits nobody.

Option 1 is the only tenable option, but even this suggestion has its limitations. While the most timely and flexible, it still is too rigid in terms of disclaimer language. Standardized language where the factual patterns vary with each ingredient and each body of science are not helpful. Each body of literature is specific to the facts of the ingredient/disease endpoint tested – mandating standardized language precludes the most accurate and factually specific information from being presented to consumers. The reason FDA is struggling with the use of the term "may" is that it will not work for every ingredient and state of the science presented. It is also not clear, based upon past performance, that FDA can meet its 270 day deadline once the submissions begin to pile up.

Herbalife, therefore, suggests that FDA consider establishing a fourth alternative; namely, a notification procedure that would operate like that of the New Dietary Ingredient or Generally Recognized as Safe systems. In this way, a company could submit a notification to FDA stating that it is going to market in 90 days with a defined claim, and state the scientific basis for the claim. FDA would have 90 days within which to have scientists review the claim and support. A "no questions at this time" letter could then be posted on the FDA website. If FDA felt the disclaimer needed to be modified in any way, it could make such suggestions in its letter.

All of the qualified health claims notifications would be posted in the same place on FDA's website. In this way, the public would know where to look for these claims and the status of review, thus assuring transparency. Industry and the public could be kept informed of what claims are under review, and what FDA's decisions are with respect to such claims.



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Most importantly, as the science evolves, a company could continue to file submissions to the agency under the original submission, so that when necessary, the disclaimer could be modified. This will give companies the incentive to continue research on ingredients in the hope of achieving an unqualified claim at some point.

We hope that FDA will consider this Alternative Option as the most viable and workable in addressing the unique status of qualified health claims. It comports well with the Pearson directives while preserving accountabilities. Herbalife International of America, Inc. appreciates the opportunity to participate in this rulemaking.

**[DISCUSS ADDING COMMENTS ON FOOD PYRAMID  
OR DIETARY GUIDANCE STATEMENTS]**

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John Venardos", written in a cursive style.

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