



**HERBALIFE.**

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January 18, 2005

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**Dockets Management Branch (HFA-305)  
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**Re: Docket No. 2004N-0454: Premarket Notification for New Dietary Ingredients**

To Whom It May Concern:

Herbalife International, Inc. ("Herbalife") is submitting these comments to the Food and Drug Administration ("FDA") in response to the October 20, 2004 Notice, "Dietary Supplements: Premarket Notification for New Dietary Ingredient Notification" ("NDI Notification"), 69 Fed. Reg. 61680.

Herbalife recommends that (1) FDA needs to clarify the effect of changes on the status of ingredients under the NDI section and (2) FDA should establish a system where data and information submitted in an NDI remain confidential and where exclusivity is granted in exchange for filing notifications.

As a science-based innovator, Herbalife develops and markets conventional foods, dietary supplements and cosmetics that promote healthy living. The company was founded more than 25 years ago in California, reported \$1.2 billion in net sales for 2003 and offers more than 150 different products to consumers around the world. Herbalife's products are marketed through a global network of more than 1,000,000 independent distributors in 59 countries.

Herbalife supports full implementation of the Dietary Supplement Health and Education Act of 1994 ("DSHEA") in ensuring dietary supplement safety. Thus, Herbalife applauds FDA's current effort to clarify and enforce the section of DSHEA pertaining to new dietary ingredients ("NDIs"), which is codified at 21 U.S.C. §350b.

Herbalife believes there are a number of issues relating to NDIs that need to be resolved. For example, Herbalife asks FDA to clarify changes to "grandfathered" ingredients or existing NDIs that would cause them to be regarded as NDIs, subject to the notification requirement. Moreover, Herbalife urges FDA to seriously consider incentives that could be granted for filing NDIs, including increased confidentiality of filing data as well as modes of providing exclusivity to the filing company.

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**I. FDA Needs To Clarify The Effect Of Changes On The Status Of Ingredients Under The NDI Section**

The NDI section defines a “new dietary ingredient” as “a dietary ingredient that was not marketed in the United States before October 15, 1994.” 21 U.S.C. §350b(c). By implication, dietary ingredients that were marketed in the United States before October 14, 1994 – commonly referred to as “grandfathered” ingredients – are not subject to the NDI notification requirement outlined in 21 U.S.C. §350b(a)(2).

While this definition has been useful in providing a mechanism for assessing whether a dietary ingredient is *new*, it leaves the door open to additional questions. For example, the statute does not speak to whether changes in extraction method, concentration, or chemical composition of a “grandfathered” dietary ingredient would cause it to be considered “new” under the statute, triggering an NDI notification requirement.

The statute also is not clear on whether an *additional* NDI notification would be required following changes in concentration or chemical processing for an NDI that had already been the subject of a notification. For example, if a company filed a notification for a dietary ingredient X at a certain concentration or following a certain extraction methodology, it is not clear whether an additional NDI notification would be required for the same chemical entity X at an increased concentration or following a different processing methodology.

Herbalife takes the position that an NDI should not be required for every change in extraction method, concentration, or chemical composition of a “grandfathered” ingredient, nor for every change in concentration or chemical processing of an existing NDI. Such a requirement would be burdensome and would provide a disincentive for companies to invest in improvements in technology.

Instead, FDA should heed the fact that the NDI notification requirement is geared to ensuring safety. Thus, an NDI should only be required for changes in extraction method, concentration or chemical composition of a “grandfathered” ingredient or for changes in concentration or chemical processing of an existing NDI *if that change materially affects the safety profile of the dietary ingredient*. This approach would ensure safety, while minimizing the burden on companies that strive to improve dietary ingredients.

Commensurate with existing practice under the NDI section, the responsibility for making this safety determination would fall, in the first instance, on the ingredient supplier, manufacturer *or* those placing the altered dietary ingredient in commerce. If FDA subsequently disagreed with the approach taken, it would then take appropriate enforcement action against the company responsible for placing the ingredient in commerce.

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**II. FDA Should Establish a System Where Data and Information Submitted in an NDI Remain Confidential and Where Exclusivity is Granted in Exchange for Filing Notifications**

FDA needs to recognize that the quality of scientific research – and hence safety data – generated for an NDI is tied to the incentives for filing an NDI notification. Therefore, it is critical that the agency seriously consider confidentiality and exclusivity as part of its response to NDI notifications.

Companies that develop NDIs spend significant amounts of capital developing ingredients and generating information about safety and efficacy. At present, when a company files a notification for an NDI, it runs the risk that – depending on FDA's response to trade secret claims – some or all of this data will become public information. This effectively allows other companies to market the same ingredient in reliance on the NDI notification and undermines the company's investment.

To counter this inequity, Herbalife urges FDA to ensure that information submitted as part of an NDI notification will be confidential. Instead of releasing most – or all – of the file to the public docket after the 75 day waiting period, FDA simply could publish the company name and the chemical or species name of the dietary ingredient. Other companies would have information that a NDI had been reviewed by FDA, but would not have access to the data and information allowing them to easily market copycat products. This approach would go a long way toward alleviating companies' concerns that filing an NDI notification effectively undermines the research investment made.

In addition, FDA should consider exclusivity as an incentive to companies that file NDI notifications. At present, there is a strong disincentive to file an NDI notification because competitors are equally able to rely on FDA's response. By granting some period of exclusive reliance to those companies who underwrite the cost of filing a NDI notification, FDA would substantially improve compliance and the quality of submissions.

Herbalife recognizes that, as written, DSHEA does not provide for such exclusivity. Nonetheless, the company urges FDA to explore *de facto* or *de jure* methods of granting such exclusivity.

**III. Conclusion**

Herbalife appreciates FDA's ongoing efforts to review and clarify obligations under 21 U.S.C. 350b. At the same time, Herbalife urges the agency to take the necessary steps to increase the incentives for companies to comply with DSHEA.



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Sincerely,

A handwritten signature in black ink, appearing to read "John W. ...". The signature is fluid and cursive, with a long horizontal stroke at the end.