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April 2, 2003 1575 '03 APR -3 A9:05

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

Re: Docket No. 02N-0276: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5378 (Feb. 3, 2003)

To Whom It May Concern:

Herbalife International of America, Inc. ("Herbalife") is submitting these comments to the Food and Drug Administration ("FDA") in response to the February 3, 2003 Proposed Rule "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," 68 Fed. Reg. 5378 (Feb. 3, 2003).

For over 23 years, Herbalife has marketed scientifically formulated conventional food, dietary supplements and personal care products through a network of independent distributors in 57 countries worldwide. Each of our 150 products is produce to our exacting specifications by various domestic and international state-of-the-art contract manufacturers.

Like some other direct sales companies, Herbalife distributes its products through an integrated distribution system, in which the company sells products to independent distributors. Within the United States, as of February 28, 2003, we had more than 263,000 independent distributors, virtually all of whom consume our products. Additionally, within the United States, as of February 28, 2003 Herbalife had nearly 42,000 independent distributors qualified as "Supervisors," who may be holding our products in inventory for sale to other individuals who also may be independent distributors. The vast majority of these "Supervisors" are also consuming our products.

Herbalife recognizes the importance of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and supports FDA's efforts to collect information relevant to tracking potential bioterrorism events. Nonetheless, the Company asks that FDA clarify a key provision of the proposed rule in order to ensure that our large number of "Supervisors" would not have to register as facilities with the agency, simply because they hold quite often for only transient periods our conventional food and/or dietary supplements for sale to other distributors or consumers.

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I. **The Proposed Rule Does Not Address Direct Sales Companies Selling Through Global Networks of Independent Distributors**

As written, the preamble to the Proposed Rule does not explicitly state how the registration requirement would apply to direct sales companies such as Herbalife. Rather, it focuses on alternate facilities, including retailers selling directly to consumers, wholesalers and warehouse clubs. By not addressing the other variations on product distribution, the preamble creates confusion about the rule's applicability to direct sales companies such as Herbalife.

The preamble states:

The proposed rule would also require facilities that sell both directly to consumers and to distributors and wholesalers to register. Examples of these facilities are warehouse clubs. Because such facilities do not sell food directly to consumers only, they do not meet the definition of a "retail facility." 68 Fed. Reg. 5383.

This language raises the possibility that FDA may contemplate mandatory registration for all parties who do not only sell to consumers, including independent distributors affiliated with a direct sales company such as Herbalife.

Herbalife's thousands of domestic and international distributors are independent individuals, not facilities. While known within the direct selling industry as "distributors," they are not classic distributors as defined in the Federal Food, Drug and Cosmetic Act nor as defined by typical state wholesale registration laws. We seek clarification that FDA does not intend to apply the registration requirement to individual independent distributors affiliated with a multinational direct sales company such as Herbalife that sell its products both to consumers and to other distributors. Absent such a clarification, this provision of the Act may trigger nearly 42,000 individual registrations by our independent distributor "Supervisors" alone, and still additional registrations by others who further distribute our products down the line.

The consequence of such a rule is overwhelming, both to individuals who may be asked to register with the FDA, and to the FDA that would have to process tens of thousand of individuals who generally distribute no more than a handful of products to other individuals often on an irregular basis. Moreover, such a requirement would not contribute additional useful information about the source of our conventional food or dietary supplement to FDA. The rule is written in such a way as to ensure that the agency already receives product identification and source information about Herbalife products via the registration filed by the company itself.

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Registrations by individual independent distributors would only flood FDA with inconsequential details as to thousands of transactions involving small numbers of products shared between individuals, friends, family or neighbors.

In addition, a registration requirement applicable to Herbalife's independent distributors would overwhelm and potentially deter those individuals from participating in Herbalife's direct sales marketing program. These entrepreneurs tend to be individuals without extensive corporate or commercial experience who would likely be put off by excess government reporting requirements.

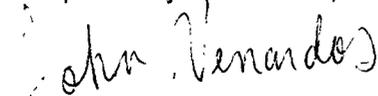
II. Herbalife Requests Clarification that the Registration Requirement Does Not Apply to Individual Herbalife Distributors

Herbalife urges FDA to add an exemption to the Proposed Rule's registration requirement for distributors operating within an integrated distribution system, such as Herbalife's independent "Supervisors," who market our products to other distributors. This exemption would apply to individual distributors involved in distribution to other individuals as well those who are themselves end-use consumers. Proposed wording of such an exemption might state:

"The foregoing provisions requiring the registration of facilities would not apply to individuals who independently distribute or sell food [including dietary supplements which, for the purposes of regulations are considered as a subcategory of food] to other distributors or to consumers."

Herbalife believes firmly in the goals of food safety outlined by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and FDA's Proposed Rule. However, the company asks that FDA make clear that the requirement does not apply more broadly than necessary to ensure the safety of the U.S. food supply.

Respectfully submitted,



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