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August 10, 1999

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

[Docket No. 99N-1174]

Re: Regulation of Dietary Supplements; Formulating Public Policy re  
Unethical/Illegal Marketing of Supplements

Dear FDA:

Jarrow Formulas is a supplier of dietary supplements and has been in business since 1976.

As with any channel of commerce, there will always be individuals who will operate outside of the standards of law or business ethics, including dietary supplements. However, regulations should not be formulated to the lowest standard of conduct as being the basis on which standards should be established. The result of such an approach will be to burden the entire affected industry as well as punish the public by depriving them of the goods, information and services they seek.

The FDA has received a number of complaints from "consumer advocates" about the supposedly "unregulated" nature of this industry. A meeting was held July 20, 1999 in Oakland, where the usual complaints were raised. True to form, the complainers cited the worst case examples seeking to taint the entire industry. Needless to say, these naysayers cite no examples of the millions of people who take supplements and receive benefit from them.

The first point to be made in response is that these "advocates" grossly exaggerate the problem. Even if they had no "worst case" examples to cite, such as an inappropriate claim for a "testosterone precursor," they would still bitterly grouse about normal structure and function claims such as "supports joint tissue" made on behalf of glucosamine products. These people simply gripe about everything. Frankly, there is no satisfying them except to put the supplement business out of business.

The second issue that needs to be addressed is whether the FDA has been doing its job. Frankly, I believe that there are elements in the FDA that do not want the agency to take any action at all so that the case can be built against the industry, that there are "all these problems." As an example, Jarrow Formulas spent over four years in litigation against a real con artist, Boyd O'Donnell and his "companies," Biogenesis, Inc. and its successor International Biotech USA, Inc. The FDA had raided them in April, 1994 for contamination by pseudomonas and illegal drug claims. The agency never followed up

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on the raid with a prosecution; my company publicized the raid; Biogenesis sued my company and we countersued. They lost their suit and Jarrow obtained a court ruling that the company had engaged in false advertising. The California State court judge (arbitrary by nature and woefully ignorant of federal food and drug law) ruled that Biogenesis was not selling an "unapproved new drug" and also against the RICO claims we had also filed against this twice-convicted felon (for perjury) and tax cheat. (Biogenesis, as your OCI knows, was making blatant anti-candidiasis claims directed at immune-suppressed persons which as you know is an unapproved drug claim. The judge never explained the basis for his ridiculous ruling.) Simply in order to get the FDA to authenticate its own documents, my attorney had to contact Congressman Waxman's office to intervene with the agency. The agency's inaction on the one hand and unwillingness to cooperate on the other speak fathoms about the disingenuous protestations of the agency regarding regulation of dietary supplements. The inexcusable failure of the agency to act in this matter is heightened by the fact that FDA's affidavit for a search warrant for the April, 1994 raid even stated that the intended microorganism of the product - B. Laterosporous - could be harmful.

In the same regard, the agency has embarrassed itself regarding young adult athletes who supposedly injured themselves with creatine when in fact, they died of heat exhaustion because they put on sweat suits and went into a sauna determined to "make weight" for the wrestling category they sought at any price - apparently with their lives. But the FDA blamed creatine and the misinformation was reported in the general press - repeatedly. The FDA has a habit of grossly exaggerating any incident where a supplement *might* be involved and then fails to make a retraction once the allegation is disproven.

Third, the FDA could send out press releases regarding some of the egregious offenders. A little negative publicity would go a long way toward reducing the ability of these companies to market their products. Legitimate retailers will not wish to carry such products. If sold on the Internet, the Federal Trade Commission has been active in regulating illegal activities.

In summary of this issue, if conduct is illegal, then the agency should enforce the law. Generally, if a tactic is unethical, it is also illegal and further regulations are not needed. Sometimes, however, there may be no ready answer without implementing a suffocating over-response, but that is the nature of a less-than-perfect world.

\* \* \*

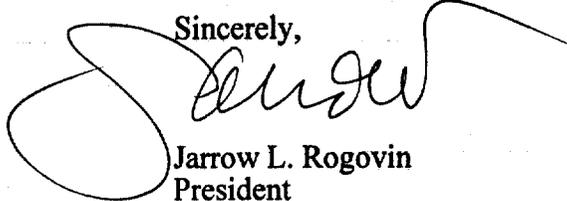
At the risk of seeming trite, Jarrow Formulas acknowledges that we do not live in a perfect world but it is one in which the road to hell is paved with "good intentions." Another applicable bromide is not to throw out the baby with the bath water.

FDA Commissioner Dr. Jane Henney stated at her Senate confirmation hearing that the agency does indeed have sufficient tools to regulate the supplement industry. Assuming that the good doctor was not patronizing Senator Harkin, Jarrow Formulas takes the honorable Commissioner at her word and reminds the agency that at all times it has all legal authority and tools at its disposal needed to protect the safety of the public. It also has the "bully pulpit" of the press release and the general cooperation of the dietary supplement industry.

In conclusion, if the FDA spent the time, money and energy that it does to seek complaints -- such as sponsoring forums for such complaints -- on enforcement and

education instead, the relatively minor problems relating to the supplement industry would be further diminished. In other words, the lid could be put over this tempest in a teapot with far less effort than the Center for Science in the Public Interest and its drouges otherwise desire in their zeal to reduce this industry to nothing more than low dosages of vitamins and minerals that would be recategorized as OTCs.

Sincerely,

A handwritten signature in black ink, appearing to read "Jarro L. Rogovin". The signature is fluid and cursive, with a large loop at the beginning and a long, sweeping tail that extends to the right.

Jarrow L. Rogovin  
President

cc: Congressman Henry A. Waxman

P.S. At the August 4, 1999 hearing on the definition of disease and structure and function claims, I asked the CSPI lawyer what type of S&F claim she would propose for carnitine. As I anticipated: 1) She didn't have a suggestion; and 2) She said she was "a lawyer, not a scientist." But, I countered, that didn't stop her from being on a panel and having the gall to tell the FDA how to regulate a whole industry for the whole country - with its international implications. Perhaps the agency should stop being so impressed with these incessant complainers. They have little knowledge of the subject they seek to have so heavily regulated.

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