March 25, 2002

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VIA E-MAIL AND FEDERAL EXPRESS

Office of Information and Regulatory Affairs, OMB,
Attn: Desk Officer for FDA
New Executive Office Bldg.
725 17th St. NW., rm. 10235
Washington, DC 20503
Attn: Desk Officer for FDA

Re: Comments of Jarrow Formulas, Inc. on FDA's Consumer Survey as to Label Claims of Foods and Supplements; Docket No.: 02N-0063

Dear Desk Officer for FDA:

Patton Boggs LLP represents Jarrow Formulas, Inc. ("JFI"), which is a Los Angeles-based company that develops, manufactures, markets, and sells dietary supplements. JFI, therefore, has an interest in determining precisely how consumers interpret label claims, especially claims and symbols on dietary supplement labels. Thus, JFI applauds the Food and Drug Administration ("FDA" or the "Agency") in its current consumer survey project, which seeks to determine how label claims on foods and dietary supplements are actually viewed, read, and interpreted by the consumer in practice. JFI is especially interested in how consumers read and interpret a certification or quality seal or logo on a product label—both with and without a disclaimer. On behalf of JFI, we offer the following Comment, which is focused on point (3) of the Federal Register Notice of February 21, 2002: "ways to enhance the quality, utility, and clarity of the information to be collected." (Emphasis added.)

Introduction to JFI's Position on Seals and Logos as Label Claims

JFI's position is that certification seals and logos constitute label claims that directly or indirectly promote: the quality, safety, purity, naturalness, and/or efficacy of the product bearing that seal or logo on the label. In this Comment, we believe that the most important input we can provide to the Agency consists of our proposed questions for the survey, which are included herein. However, we also believe that it is important for the FDA to understand and appreciate JFI's concerns about the many dietary supplement certification programs and seals which are proliferating, and which have been engendered in part by the absence of an official Final Rule on

GMPs for dietary supplements from this Agency. The dietary supplement industry—and the consumer—now has to contend with certification programs and seals or logos from:

- the National Nutritional Foods Association ("NNFA") GMP Certification Program and Seal
- the National Sanitary Foundation ("NSF") Dietary Supplement Certification Program
- the United States Pharmacoepia (U.S.P.) testing and seal
- ConsumerLab.com Product Review and "Approved Quality" Seal
- A.C.E.R.I.S. (Academy of Clinical, Environmental, Research and Informational Sciences)

What one commentator has termed the "alphabet soup" of seals is extremely confusing, misleading, and actually deceptive to the reasonable consumer. JFI feels most strongly about the misleading character of the NNFA GMP seal, for the reasons set forth below; and recently the NNFA has partnered with the NSF, so that certified companies may use a double seal. In addition, the NNFA requires a disclaimer to be used with its GMP seal (also discussed below), but this disclaimer—rather than truly disclaiming any express claims or implied claims made by the seal, and rather than curing the problem of a misleading seal—actually renders the NNFA GMP seal either contradictory, or deceptive, or both.

The recent statement of Lester Crawford, Deputy Commissioner of the FDA, quoted in *The Nando Times* (Online), concerning the labeling of GMO foods is equally applicable to JFI's concerns with respect to certification seals for dietary supplements. Mr. Crawford stated, "If it's on the label, it has to be true, and it's up to us [FDA] to be sure that it is." *The Nando Times* (Online), Phillip Brasher, AP Farm Writer, March 21, 2002. [Bracketed material added.]

JFI Concerns as to Certification Programs and Seals Generally

The seals and logos which are the subject of this letter are indeed label claims, are also misleading and deceptive representations, and are vitally important to and influence millions of consumers of dietary supplements, as well as retailers. In 1996, a survey by New Hope Natural Media and The Hartman Group concluded that, in 1997, 70% of all American households purchased dietary supplements. FDA's Final Rule on Structure-Function Claims, 65 Federal Register 1000, at 1048 (Jan. 6, 2000). In March of 1999, the FDA's estimate was that dietary supplement sales in 1997 were $12.7 billion. "Economic Characterization of the Dietary Supplement Industry - Final Report" at p. 4. These numbers have increased in the past four years. As sales of supplements increase, the number of products bearing certification seals or quality seals on the label have also increased. Consequently, the consumer is confronted with a variety of seals on product labels—some accompanied by disclaimers and some not, some disclaimers in prominent print and some not.

First, logo-based certification programs have the tendency, if not the actual effect, of diluting corporate and brand names. Since the NNFA has been blatantly coercive in promoting its seal, the dilutional effect is highly objectable. Second, Jarrow L. Rogovin, the President of JFI, has been very active in communicating to the industry the following points: (i) he believes that consumers assume that dietary supplements which are touted as being of very high quality consist only of naturally-derived (i.e., non-synthetic) ingredients; (ii) the use of a certification seal or logo is an example of a method of promotion of a "high quality" message; and (iii) not all supplements which bear such a seal or logo do, in fact, contain the non-synthetic (i.e., natural) form of an ingredient when available.[1] As a result, consumers may be misled into believing that a logo-bearing synthetic product is superior to a non-logo-bearing natural product, even though the natural product is actually superior. Risk of this confusion is heightened in situations where a company which sells natural dietary supplements refuses to adopt a certification logo for reasons of company pride and its own brand-name strength. Third, a certification logo on one product of a particular company may cause consumers to make inferences of quality with respect to other products of that company, which may not have been produced under the same standards or even in the same manufacturing facility as the logo-bearing product.

JFI is mindful that this invitation from the FDA for Comments was as to label claims, and that, in general, the FDA's regulatory province centers on labels and labeling, while the Federal Trade Commission's (FTC's) regulatory province centers on promotional materials. JFI is also aware of the shared jurisdiction and the memorandum of understanding between these two agencies, and the cooperation and synergy of the FDA and FTC in their monitoring of regulatory violations as to dietary supplements, e.g., a recent joint statement decrying both the labeling and the promotion of "Herbal Antibiotics" to combat anthrax. However, despite the difference in missions of the two agencies, JFI's position is that certification seals or logos on dietary supplement labels become clearly promotional, and this is one of the many causes for its grave concern.

NNFA GMP Certification Program and Seal

The NNFA Board of Directors developed its own GMP program between 1997 and 1999 (the "NNFA GMP program" or "program") in a attempt at industry self-regulation. Instead of the program consisting of educational development and training appropriate to a non-profit trade association, the NNFA undertook the creation of a commercial program to be used in labeling. Accordingly, the NNFA GMP program was inaugurated publicly on July 10, 1999, with a press conference at the Association's annual convention and trade show, MarketPlace'99 in Las Vegas. In an article dated two days later, July 12, 1999, then Executive Director of the NNFA, Michael Q. Ford, is quoted as saying, "Rather than waiting any longer for the federal government [FDA regulatory action], NNFA decided to take action to ensure consumer safety." See Tab 1. Despite the expression of concern for consumer safety, the NNFA's promotional

[1] Examples include vitamin E, lycopene, and S-adenosyl-methionine.

efforts have been relentlessly commercial. The two other major dietary supplement trade associations, the American Herbal Products Association and the Council for Responsible Nutrition, have not endorsed or embraced NNFA's GMPs.

The most prominent and best known feature of that program is the NNFA GMP seal. It can be placed on each product label and ad of a company which has been certified as having met NNFA's GMP requirements. This is a circular seal, approximately the size of a quarter, bearing the words "Good Manufacturing Practices" in small type above the acronym GMP in large letters, as well as the NNFA acronym. See NNFA brochure which is attached at Tab 2. Before the seal can be used on a product label or in an ad, the company which wishes to use it must be certified by the NNFA; the actual manufacturer of the product if the supplier itself does not manufacture that product, must also be certified. An audit, which is a prerequisite for certification, is performed by third-party inspectors selected by the NNFA. The audit results in a Level of Compliance rating which is used to determine eligibility for certification. The audit consists of a physical inspection of the premises and an assessment of the applicant's manufacturing procedures in relationship to the NNFA's GMP standards. The NNFA briefly describes the applicant's audit in a publication entitled NNFA GMP Certification Program Overview. See Tab 3. No testing of raw ingredients or of finished products is performed by the inspectors. The NNFA certification lasts for a *full three years.* A certified member could use the GMP seal on every product label and in every product ad for that period of time, including on any new products, without any interim inspection or audit by the NNFA or a third party inspector.

As a consequence of several complaints from JFI during 2000, the NNFA adopted two disclaimers which are to be used with the NNFA GMP seal. They are:

First Disclaimer: "This Seal certifies that the manufacturer of this product uses quality systems and procedures that comply with NNFA's Dietary Supplement GMP standards. The quality of individual ingredients, however, has not been certified."

JFI first requested such a disclaimer from the NNFA in October of 1999 and followed that request with a series of letters in support of such a disclaimer. This disclaimer was approved by the NNFA Board in April of 2000, announced on June 6,and made effective as of June 1. The NNFA, in its September 2000 issue of NNFA Today, discussed the seal and this disclaimer. See Tab 4. Among other things, the NNFA established some disclaimer compliance deadlines. In addition, JFI pointed out to NNFA that some products bearing the seals on the label were actually manufactured off-site, at a facility that had not been GMP audited or certified. NNFA eventually responded with a second disclaimer.

Second Disclaimer: "Some products of the company have not been manufactured at an NNFA certified facility." See para. 8 of Tab 5.

NNFA's Weak Disclaimer Is No Cure for Deceptive NNFA GMP Seal

JFI has vigorously and adamantly insisted from the beginning of this NNFA GMP program that the program was fatally flawed, and that the seal was dishonest and constituted false advertising. JFI has argued for many reforms, short of dismantling the entire program. From the beginning, July of 1999, JFI has maintained to NNFA, its President, its Board, and its legal counsel, that *at the very least a clear disclaimer about the seal's message was essential.* However, it became clear that the commercial aspects of the NNFA's program were fatally flawed, and that the association should confine its activity to education and training as properly befitting its role. See correspondence at Tab 6.

At first, NNFA's position was that no disclaimer was necessary. After much resistance, the NNFA finally agreed to require a disclaimer, but adopted one which is confusing and misleading to consumers, and which does not disclaim all the misleading implied claims of the seal. Next, JFI wrote to the NNFA with concerns about enforcement of the disclaimer. Then, again only after exhaustive, vigorous urging from JFI, NNFA set in place some enforcement guidelines for monitoring of the required disclaimer; however, no actual surveillance is part of these guidelines.

By letter dated March 29, 2000, Jarrow L. Rogovin, President of JFI, proposed the following as an adequate disclaimer, which was never accepted:

> **Neither the quality of the individual ingredients, the product, its safety, nor the accuracy of the label have been certified. This seal certifies only manufacturing cleanliness and record keeping procedures.**

Instead, the disclaimer finally approved by the NNFA is:

> This Seal certifies that the manufacturer of this product uses quality systems and procedures that comply with NNFA's Dietary Supplement GMP standards. The quality of individual ingredients, however, has not been certified.

The NNFA's disclaimer which is set out above is misleading because:

1) The first sentence omits the material statement that not all of the company's facilities have been certified. An accurate statement of the true circumstances is: ". . . the manufacture of this product uses quality systems and procedures . . . at the facilities that have been audited."

2) The second sentence omits the statement that other aspects besides the quality of the individual ingredients have also *not* been certified.

3) The second sentence omits the statement that the quality of the finished product as a whole has not been certified.

4) The second sentence omits the statement that the purity of the finished product as a whole has not been certified.

5) The second sentence omits the statement that the safety of the finished product as a whole has not been certified.

6) The second sentence omits the statement that the accuracy of the label has not been certified.

7) The second sentence omits the statement that the effectiveness of the product has not been certified.

8) The second sentence omits the statement that the superiority of the certified company's products, as compared to the products of dietary supplement companies which do not bear the NNFA GMP seal, has not been established or has not been certified.

9) Consumers and most NNFA retailer members do not have any idea what the phrase "NNFA GMP standards" actually means.

JFI is confident that if the FDA and OMB include questions about the NNFA disclaimer in the consumer survey (please see proposed questions below), consumer confusion will be evident in the responses.

The paradox of the primary disclaimer is that the number of words which are needed to inform consumers clearly of the limited nature of the true claims conveyed by the seal would result in a disclaimer so lengthy that the average consumer would not read it. For example, a truthful disclaimer for the NNFA GMP seal would have to read:

> This seal certifies only that the manufacturer complied with NNFA's GMP certification program at one point in time. There has been no NNFA audit of this particular product, no ongoing review of the manufacturer by NNFA or any other organization, and no independent verification or validation of any process by an outside laboratory or other third party. Further, NNFA has not reviewed the product label, including any of the statements, claims or assertions contained thereon. Thus, NNFA makes no warranty or guarantee whatsoever as to the safety or quality or any other characteristics of the ingredients or formulation of the product.

The primary disclaimer which was adopted for use with the seal does not reasonably inform consumers of the true meaning of the NNFA GMP seal.

In summary, disclaimers were reluctantly adopted by the NNFA following months of unrelenting pressure by JFI and some other supplier members. These disclaimers are required to appear in close juxtaposition to the seal on the actual label, but this requirement is neither monitored nor enforced.

Claims Made About The NNFA GMP Seal (Logo)—Safety and Quality

The NNFA has distributed a glossy tri-fold brochure promoting its GMP program. See Tab 2. The brochure states prominently and in bold type, "When you see NNFA's Good Manufacturing Practices seal on the label of a dietary supplement, you can be confident of that product's safety, quality and purity." The brochure further states, "Consumers will finally have independent verification that the products they buy are safe and reliable." and – also in bold type – "Assuring the public of product safety and reliability is a key objective of the National Nutritional Foods Association." Finally, on the brochure's cover, above a picture of the GMP seal, there appears, in large bold letters, a statement that confirms that the seal is a seal of approval and a guarantee by the NNFA: **"What you see on the label, Is what you get in the product . . ."** [bold in the original]. In NNFA's literature, the GMP Certification Program, an "Overview" of the program includes the statement: "*This program ensures that all elements of the manufacturing process are reviewed* to provide assurance that safety and quality is built into products during manufacture." (Emphasis added.) See Tab 3. Furthermore, in a flier advertising the NNFA seminar on "Preparing for Certification", the NNFA states: "The GMP Certification Program underscores our members' commitment to quality and brings that message to consumers through the use of the GMP seal." See Tab 7. Further, the "GMP" seal, by its nature, implies safety. Despite these claims, our client has registered protests with the NNFA concerning several products containing ingredients in less than label claim amounts from companies utilizing the GMP logo.

The NNFA's own literature demonstrates that only the manufacturing *processes* are reviewed; it is not the case that any finished products are tested by the NNFA or the third party auditors. Thus, any assurances of product safety and quality, whether direct or implied, are false. The program merely certifies – and the seal represents – that a manufacturer supposedly has a system in place, at the time of the audit, which complies with NNFA's manufacturing standards. As Michael Q. Ford, the former President of NNFA, said in his letter to JFI's President on August 25, 1999, "The GMP logo certifies that the facility at which a dietary supplement has been produced has met NNFA's GMP standards for dietary supplements."

Because of these express and implied representations of safety, reliability or quality and efficacy, one assumes that the FTC, for example, would require the manufacturer and NNFA to possess and rely upon competent and reliable scientific evidence that each product carrying the GMP seal is safe, reliable, and effective for all purposes indicated in advertising and on the label. In many instances, such representations of safety, quality, or reliability and efficacy would be false and misleading. Similarly, because these same representations are made as label claims, and

because consumers will "read into" the seal implied claims of quality, safety, and efficiency, the FDA must monitor and restrict the use of certification seals in some way.

The NNFA does not screen products for categories of ingredient – or amounts – that should not carry the seal.

False and Misleading Label Claims Through Use of the NNFA GMP Seal Through Ads

Advertisements containing, describing, and touting the seal define its meaning for consumers – a false meaning of quality. Ads reinforce and bolster label claims; there is a reinforcement of deception here, especially when products with the seal on the labels are depicted in the ads. Claims by some certified supplier members of NNFA in some promotional materials are false and misleading. For example, one such "certified" company is Consac Industries, Inc., d/b/a Country Life Vitamins, Inc. This company has advertised aggressively its "NNFA GMP" status in trade magazine ads, with neck hangers put on thousands of individual bottles. One such ad, in the March 2000 issue of the Natural Foods Merchandiser, starts with a banner headline and goes on to make several deceptive claims:

> MAKE SURE . . . *Your Supplements Are* **GMP Certified!** And with Country Life you can be sure about what you're getting. That's because Country Life supplements are manufactured to insure they meet the highest standards, standards set by the National Nutritional Foods Association. The *"GMP" Quality Seal* let's [sic] you know that Country Life has met these standards and produces the finest supplements available. So, "Make sure" your customers look for the *Seal of Approval* they can trust. **"GMP"**.

(Bold font and quotation marks are in the original.) The claims of this ad imply that Country Life's dietary supplements are approved by the NNFA.

JFI has compiled several other examples of deceptive use of the NNFA GMP seal by certified supplier companies, in print ads and websites. See at Tab 8. JFI filed several complaints with the NNFA about a number of Country Life's products being mislabeled despite claims that these products were GMP-certified. As a result of these complaints, the company was compelled to change its labeling and the formulations. JFI has no reason to believe that other Country Life products bearing the seal on their labels are not mislabeled. JFI's point in this comment is that institutional ads such as these reinforce – in the consumer's mind – false meanings of the seal which are then transferred and imprinted to products bearing that seal on the product labels.

As a result of some certified companies' misuse of the seal, it appears to consumers that many products *per company* are "approved" by the NNFA. However, no actual independent testing by the NNFA or its auditors was ever performed on final products, e.g., a chemical

analysis of the potency of a product or its ingredients, or even a test for the presence in the container of all ingredients which are declared on the label. As a further result of the misuse of the seal, products are permitted to carry the "NNFA GMP" seal that are not true-to-claim. For instance, although the label could declare that a dietary supplement contains 50 mg of an herb, it might contain only 20 mg of that herb. In such a case, the NNFA GMP seal conveys to the consumer assurances of product quality and label accuracy that do not exist.

Indeed, some of the survey questions proposed below seek to clarify consumers' interpretation of the seal's value. This is in addition to the underlying problem of a non-profit association attempting to coerce its own members into co-labeling and diluting their corporate brand while at the same time this non-profit association illegally confers a benefit to select members to the detriment of a majority of its membership.

Other Programs and Seals may have more integrity, but still lead to consumer confusion. The NNFA GMP Program is in stark contrast to other certification programs in the dietary supplement industry. The ConsumerLab.com Product Review, like the NNFA GMP Program, utilizes a seal that may be used by manufacturers who have met certain criteria, but is specific to the product only. Unlike the NNFA seal, the seal is less likely to be generalized to the entire company. Unlike the NNFA program, ConsumerLab.com Product Review *tests individual products* pursuant to five *ingredient-related* criteria to determine whether the tested products are eligible to bear the ConsumerLab.com "Approved Quality" Seal. These ingredient-related criteria -- tested in a laboratory -- are much more reflective of individual product quality than are the manufacturer's record-keeping practices, which is the type of criteria that is audited pursuant to the NNFA GMP Program. The ConsumerLab.com "Approved Quality" Seal makes clear, on the Seal itself, exactly what has been certified: for example, if a Ginkgo Biloba supplement was tested, the seal will bear the words "Ginkgo Biloba" on the lower portion of the seal; if a multivitamin was tested, the word "multivitamin" will appear on the lower portion of the seal.

In contrast to NNFA's program, other certification programs use experts in the field to test individual product quality, and then approve seals to convey to consumers in a truthful and non-misleading way exactly what the program is certifying. Unlike this, the NNFA GMP Program misleads consumers to believe that the products of NNFA GMP-certified companies are of high quality when, in fact, the quality of those finished products has never been tested. (See pages taken from the ConsumerLab.com website, providing specific details of the ConsumerLab.com Product Review, at Tab 9.) Apparently, ConsumerLab.com also maintains surveillance on safety issues such as serving size Upper Limits ("ULs") when permitting certification. The NNFA seal has been used even though in some cases, ULs have been substantially exceeded, e.g., 30 mg of manganese per serving.

However, due to the inferences of quality and superiority which consumers will inevitably draw when they view certification seals on dietary supplement products, JFI seriously questions

whether *any* seal or certification program can be implemented in a manner which is truthful and not misleading.

Ineffective Enforcement of the NNFA GMP Program and the Disclaimers

There are several problems with NNFA's 17-paragraph Announcement entitled "Terms of Use of NNFA GMP Certification Seal." See Tab 5. *First*, the document is internally inconsistent and reflects a profound misunderstanding of what the NNFA GMP seal actually means and conveys to consumers. The first paragraph begins, "The GMP Seal is a symbol certifying that NNFA's GMP standards, which are designed to *assure dietary supplement product* integrity and *quality*, have been satisfied at the pertinent facility (or facilities)." (Emphasis added.) Yet the first disclaimer, quoted in paragraph 9, includes the statement, "The *quality of individual ingredients*, however, *has not been*." (Emphasis added.) If the seal does not assure the quality of ingredients, then how can it purport to assure the quality of the product as a whole? This contradiction underscores one of the fundamental inaccuracies of the entire GMP program, which JFI has addressed from the beginning of its correspondence with the NNFA: The seal means only that the manufacturing practices and processes have been certified, yet it will be interpreted by consumers -- indeed, is misinterpreted by the NNFA itself, even now -- to imply certification of finished product quality.

Next, this document does not reflect any willingness or ability of the NNFA to monitor the NNFA GMP program, including institutional advertising, in any meaningful way. For example, paragraphs 16 and 17 provide that member suppliers and retailers may sell products labeled with the NNFA GMP Seal provided, among other things, that: "no verifiable information *comes to NNFA's attention* that the facility where products labeled, advertised or promoted under the GMP Seal were manufactured has fallen out of essential compliance with NNFA's GMP standards." (Emphasis added.) This condition is a type of double negative structure implying that NNFA will adopt a passive see-no-evil, hear-no-evil position, rather than a pro-active stance of rigorous and strict enforcement during the full 3 years of the certification period. JFI has located several advertisements, by NNFA GMP-certified supplier members, that either did not contain the required disclaimer at all, or contained the required disclaimer, not prominently and juxtaposed to the GMP seal, but in miniscule letters at the very bottom of the ad. See NOW Foods ad at Tab 8. Again, the *prominent* presence of a disclaimer in large institutional ads is essential to qualify and educate the consumer as to what the seal actually means *and does not mean* when the seal is present on a product label.

In short, the NNFA's weak enforcement of its seal shows that the disclaimer has been no deterrent to repeated and egregious deceptive uses of the seal as a label claim. Because this situation is unlikely to change, the protection of the consuming public against deceptive label seals is in the hands of the FDA, as well as the FTC.

NSF Dietary Supplement Certification Program and Seal

The joint NNFA-NSF GMP program and seal have grave consequences in deceptive labeling claims as well as advertising claims. Again, one of the fundamental problems with these seals is that they constitute promotions as well as labeling, and promotions that reinforce the misleading nature of the label claims. Ads can "teach" consumers that a certification seal means quality, safety, and effectiveness, when that is not in fact what the seal means.

Marketing Issues: The improper and inappropriate partnering of NSF with NNFA in a joint certification effort, results in a *double* "seal of approval." The front-page article of December's NNFA Today magazine proclaims as the first benefit of the alliance with NSF a company's "ability to: gain marketing advantage by demonstrating the quality of products." This type of commercial promotion is a serious detriment to the market-makers in the industry. "Me too" products are being placed on at least a level playing field, if not higher, by virtue of these unfair and misleading seals, even though these companies will have done none of the supporting research or marketing. A misleading double seal will undermine brand recognition and strong trademarks of many well-respected companies in the industry. Further, JFI's position is that the scientific focus of the industry is on new information about dietary supplement products and even new molecules, and this joint GMP program diverts consumer attention away from product development and towards the commercial promotion of seals. In addition, this intrusion into marketing and co-branding undermines the financial health of health food stores, which make up much of the industry's membership, because consumers will be in effect told that their loyalty to health food stores is irrelevant. Further, confused consumers seeking some simple test are likely to buy the lowest priced product bearing both seals.

Scientific Issues: Certification programs for dietary supplements raise numerous complex issues. These same types of issues do not arise to the same extent when NSF tests and certifies other types of products according to straightforward standards promulgated by the FDA, such as NSF's testing and certification of bottled water. Since the NSF and NNFA certification logos will convey a message of quality to consumers, the testing of certified products by NSF should incorporate methods and analyses specifically designed to assure the quality of finished products. Such testing of dietary supplements, however, is enormously complex. For example, the testing of probiotics for purity and potency involves complicated laboratory issues which must take into account the importance of strain selection or other related production issues that truly determine quality and effectiveness. The testing of herbal or other botanical ingredients is likewise complicated, including identifying the correct species of plant, the plant part used, and assuring the potency of the active constituents, and should be conducted by qualified herbalists. From information and documents provided by the NSF itself, we have learned that the NSF Dietary Supplement Certification Program does not include this level of testing on probiotic supplements, and NSF does not employ a single herbalist to conduct the aforementioned qualitative testing of botanical ingredients. Furthermore, vitamin and mineral supplements are subject only to quantitative testing under the NSF program, but are not subject to qualitative

testing. In short, NSF's testing and certification of dietary supplement quality is more scientifically complex than NSF realizes and requires the skills of professionals who are not involved in this process.

Legal Issues: In addition to scientific and marketing concerns, JFI has the following legal concerns about a dual NSF NNFA seal – especially the use of such seals with no disclaimer.[2] In this context, it is significant to note that the cover article about the strategic alliance in the December issue of NNFA Today magazine repeatedly states that the NNFA GMP seal indicates product quality. Yet NNFA's disclaimer, which was required to be placed in juxtaposition to the GMP seal--after JFI's repeated urging that a disclaimer was necessary--explicitly discloses that the GMP seal certifies procedures only and not quality of ingredients or of the finished product. That disclaimer, which is nowhere printed or even mentioned in the December 2001 article, reads as follows:

> **This Seal certifies that the manufacturer of this product uses quality systems and procedures that comply with NNFA's Dietary Supplement GMP standards. The quality of individual ingredients, however, has not been certified.**

Furthermore, in the attached print advertisement, taken from the October 2001 issue of Natural Foods Merchandiser, the NNFA seal is invoked as an assurance of quality, despite the disclaimer above. See Tab 10. As we have shown above, this type of claim—whether on the actual label or in a print ad--results in a false label claim and thus deception of consumers. NSF is now partnering with NNFA, and is associating itself with misleading promotional practices. Thus, one program and seal is aiding and abetting another program and seal, and is compounding the confusion for the consumer of dietary supplements. The false equation of both the NNFA seal and the NSF seal with "Quality" is demonstrated by literature distributed before and during the recent trade show, Natural Products Expo West, earlier this month in Anaheim, California. See Tab 11.

For all of the reasons presented above, JFI believes that the following proposed questions, or some form of them, should be included in the FDA's consumer survey as to the interpretation of label claims.

[2] We believe that the NNFA has embarked on a course of violating a number of FTC and IRS regulations. It seems logical to conclude that this partnering would involve the NSF in these barred activities, including deceptive advertising. These are the subjects of letters to those respective entities. .

PROPOSED QUESTIONS FOR CONSUMER SURVEY ON LABEL CLAIMS

(All of these questions pertain to the labels and labeling—catalogs, package inserts, flyers—primarily of a dietary supplement product, and primarily to the label affixed to the container.)

1. Do you read most of a label before you buy a product? Circle one:

all the time most of the time often sometimes rarely never

2. Do you read the entire label before you buy a product? Circle one:

all the time most of the time often sometimes rarely never

3. Are there any brand names or company names that are so familiar to you that you do not feel you need to read the entire label? Circle one: Yes No Sometimes

Please explain your answer, or give 1 or 2 examples: _____

4. Are there any herbal ingredients that are so familiar to you, or that you know you want to buy, such that you do not feel you need to read the entire label?
Circle one: Yes No Sometimes

Please explain your answer, or give 1 or 2 examples: _____

5. Do you read the fine print on the label? Circle one:

all the time most of the time often sometimes rarely never

6. When you are shopping for dietary supplements, how often do you look on the label for a seal or a logo? Circle one:

all the time most of the time often sometimes rarely never

7. If you are comparing two otherwise similar dietary supplement products—e.g., both contain only St. John's Wort—and one label bears a logo or seal and one does not, what percentage of the time do you decide to buy the one with the seal or logo for that reason? Circle one:

all the time most of the time often sometimes rarely never

8. On average, how much more money per container of a dietary supplement (of 30 servings) would you spend for a product labeled with a logo or seal as opposed to one not labeled with a logo or seal? Circle one:

$15 $12 $10 $7 $5 $3 $2 $1 0

9. If a brand of dietary supplement product you traditionally bought did not bear a seal or a logo, would you switch to the different brand whose label did contain the seal or logo? Circle one:

all the time most of the time often sometimes rarely never

10. Do you pay special attention to print on the label that is in bold type? Circle one:

all the time most of the time often sometimes rarely never

11. Do you pay special attention to print placed inside of a box? Circle one:

all the time most of the time often sometimes rarely never

12. When you see something that looks like a "disclaimer," how often do you read it before you buy the product? Circle one:

all the time most of the time often sometimes rarely never

13. Do you read the entire label <u>after</u> you buy the product? Circle one:

all the time most of the time often sometimes rarely never

14. When you see a seal or a logo of some sort, what ideas does that seal or logo convey to you, regardless of what the printing says? Please write 3 words that immediately come to mind: _____ _____ _____

15. What do the letters NNFA mean to you?_____

16. What do the letters GMP mean to you?_____

17. What do the letters NSF mean to you?_____

18. What do the letters USP mean to you?_____

19. What does a circle with "ConsumerLab" written inside mean to you?

_____

20. Have you seen any of the logos before? Yes No Which ones?

[Insert NNFA GMP, USP, NSF and ConsumerLab.com logos]

21. When a circle or seal contains the word "Lab" in it, what does that convey to you?

22. What's your interpretation of this symbol?

[Insert the NNFA GMP circle here, actual size]

23. When you see a seal or a logo of some sort, are you more likely to buy that product? Circle one:

all the time most of the time often sometimes rarely never

24. If your answer was one of the first four choices, why are you more likely to buy that product? Please write 1 or 2 sentences:

_____

25. When you see a seal or a logo of some sort, does that seal or logo convey the idea of purity to you? Circle one: Yes No Sometimes
Something similar? What? _____

26. When you see a seal or a logo of some sort, does that seal or logo convey the idea of "all natural" to you? Circle one: Yes No Sometimes
Something similar? What? _____

27. When you see a seal or a logo of some sort, does that seal or logo convey confirmation that the structure/function claims being made for the product, that is claims that the product has a beneficial effect on the structure or function of the body (e.g. promotes a healthy heart) are being certified?

28. When you see a seal or a logo of some sort, does that seal or logo convey confirmation that the structure/function claims are true and accurate? Circle one: Yes No Sometimes
Something similar? What? _____

29. When you see a seal or a logo, does that make you more likely to read structure/function claims,? Circle one: Yes No Sometimes
Something similar? What? _____

30. When you see a seal or a logo of some sort, does that seal or logo convey the idea of quality to you? Circle one: Yes No Sometimes
Something similar? What? _____

31. When you see a seal or a logo of some sort, does that seal or logo convey the idea of effectiveness to you? Circle one: Yes No Sometimes
Something similar? What? _____

32. When you see a seal or a logo of some sort, does that seal or logo convey the idea of safety to you? Circle one: Yes No Sometimes
Something similar? What? _____

33. When you see a seal or a logo of some sort, does that seal or logo convey the idea to you that the Supplement Facts box is especially accurate and reliable?
Circle one: Yes No Sometimes

34. When you see a seal or a logo of some sort, does that seal or logo convey the idea to you that the ingredient amounts given in the Supplement Facts box are 100% percent exact ?

Circle one: Yes No Sometimes

35. When you see a seal and some sort of disclaimer next to it, do you read them both together? What effect does the disclaimer have on the seal and vice versa. Please write two sentences explaining in your own words.

_____

36. What is your interpretation of these sentences?

This Seal certifies that the manufacturer of this product uses quality systems and procedures that comply with NNFA's Dietary Supplement GMP standards. The quality of individual ingredients, however, has not been certified.

Please rewrite them in your own words and state what they mean to you:

_____

_____

_____

37. When you read those sentences, what do you think they are telling you about the quality of the finished product?

38. After reading and interpreting the seal and the words together, a product with this seal [NNFA GMP seal] and these sentences:
This Seal certifies that the manufacturer of this product uses quality systems and procedures that comply with NNFA's Dietary Supplement GMP standards. The quality of individual ingredients, however, has not been certified.

I believe that <u>the quality</u> of this product is: (Circle one)

- Higher than products without the seal and sentences
- Lower than products without the seal and sentences
- The same as products without the seal and sentences
- Don't know
- It's confusing

39. After reading and interpreting the seal and the words together, a product with this seal [NNFA GMP seal] and these sentences:

This Seal certifies that the manufacturer of this product uses quality systems and procedures that comply with NNFA's Dietary Supplement GMP standards. The quality of individual ingredients, however, has not been certified.

I believe that the safety of this product is: (Circle one)

- Higher than products without the seal and sentences
- Lower than products without the seal and sentences
- The same as products without the seal and sentences
- Don't know
- It's confusing

40. After reading and interpreting the seal and the words together, a product with this seal [NNFA GMP seal] and these sentences:

This Seal certifies that the manufacturer of this product uses quality systems and procedures that comply with NNFA's Dietary Supplement GMP standards. The quality of individual ingredients, however, has not been certified.

I believe that the safety of this product is: (Circle one)

- Higher than products without the seal and sentences
- Lower than products without the seal and sentences
- The same as products without the seal and sentences
- Don't know
- It's confusing

41. Chose any one of your answers above that you want to give further explanation about—like: "My answer depends on other things!" Depends on what?

Please give the number of that answer and whatever further explanation you want to provide: _____

_____

Again, JFI applauds the FDA's efforts to learn more about how label claims are interpreted in practice by surveying consumers themselves, and we hope that our input proves useful in this endeavor. JFI also requests a copy of the final survey, to be sent to me at the address above. Please contact me if you have any questions about this letter or about JFI's position.

Sincerely,

Susan D. Brienza

on behalf of Jarrow Formulas, Inc.
and Jarrow L. Rogovin, its President

SDB:pah

Enclosures

cc: Jarrow L. Rogovin, President, JFI
David Seckman, Executive Director, NNFA
Kathleen Pompliano,
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Michael McGuffin, President, AHPA
Michelle Rusk, Bureau of Consumer Protection, FTC

bcc P. Scott Polisky, Esq.
Neal T. Wiener, Esq.