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August 24, 2011

Hon. Dr. Margaret Hamburg
Commissioner, U.S. Food and Drug Administration
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

By US Mail and Email

Margaret.hamburg@fda.hhs.gov

Re: Inappropriate Employment by FDA of Daniel Fabricant, Ph.D., as Director of Dietary Supplement Programs;
Request that Dr. Fabricant Be Transferred from Any Role in Dietary Supplement Regulation;
Forthcoming FOIA Request

Dear Commissioner Hamburg:

Jarrow Formulas, Inc. ("Jarrow") is a 34-year old dietary supplement company headquartered in Los Angeles, California.

As you know, the agency recently hired Daniel Fabricant, Ph.D., to be the agency's Director of Dietary Supplement Programs within CFSAN (FDA's Center for Food Safety and Applied Nutrition). Jarrow Formulas objects strenuously to the employment of Dr. Fabricant by the FDA in this role and strongly requests that he be transferred to another department in the agency or otherwise disassociated from any rulemaking or regulatory activities concerning dietary supplements or natural foods on behalf of the FDA.

As a regulatory agency, the FDA's hiring of top departmental officials must not result in a situation that in any manner constrains, intrudes or impinges upon, or can be perceived in any manner to compromise, the right or ability of the regulated industry's trade association(s) to perform its/their primary function of representing the interests of its members and the affected industry to said agency.

The acid tests are whether the individual being hired has or can be perceived to have a conflict of interest, or whether said prospective hiree would be expected to take positions and undertake actions antithetical to those espoused on behalf of the previous trade association employment, with the potential to avail himself of special knowledge of the trade association's internal workings and strategic plans, knowledge that either was or should nevertheless be

considered covered in perpetuity by non-disclosure agreements in force between this hiree and the trade association where he obtained this special knowledge and that is unethical for the FDA to make use of.

Both positions – trade association executives and regulatory officials – have an inherent fiduciary role, i.e., as a representational agent. Government must not permit itself to play the role of usurper in this regard.

In particular at this juncture, during the Comment period for the FDA's Draft Guidance on NDI's (New Dietary Ingredients), it has become clear that Dr. Fabricant has an irreconcilable conflict of interest. Dr. Fabricant's capabilities should be employed elsewhere in the agency, not in the area of dietary supplements. This letter explains why Dr. Fabricant's appointment was inappropriate, and why his continuing in his current position is untenable.

I. INTRODUCTORY SUMMARY

Because of his past employment with the Natural Products Association (NPA) as Vice President of Scientific and Regulatory Affairs, and one year as its Acting CEO, Dr. Fabricant has an insurmountable conflict of interest. This should be obvious to anyone involved in the industry including anyone at the FDA. As an officer of the trade association responsible for advocating on behalf of the industry, Dr. Fabricant was privy to discussions, ideas and opinions, which were, without question, expressed and considered by members of the industry-- with the expectation that these discussions would remain confidential. Dr. Fabricant's appointment undermines that expectation, threatens to divulge to the agency highly confidential information, including information in the nature of attorney-client privilege. Members of trade associations have an expectation of privilege and privacy in their own forum. This is particularly true when it relates to an agency often seen to be adverse to the industry and indifferent to its millions of consumers. The hiring of Dr. Fabricant represents an inappropriate historic precedent and a more than arguably improper act. The hiring cannot be said to conform to accepted standards of professional conduct.

In addition, though we are in a critical period due to the recent proposed New Dietary Ingredient (NDI) Guidance issued by the FDA, Dr. Fabricant has demonstrated a disregard for the concerns of the industry on whose behalf he once advocated and has taken positions directly contrary to those positions he previously espoused. Any decision on the proposed Guidance that involves Dr. Fabricant's participation and input will be deemed by industry to lack credibility and legitimacy. For these reasons, and those additional ones set forth below, I urge you to rescind Dr. Fabricant's appointment.

II. INAPPROPRIATE HIRING OF A TOP TRADE ASSOCIATION EXECUTIVE BY A REGULATORY AGENCY

Dr. Fabricant was employed by the Natural Products Association ("NPA," formerly NNFA, National Nutritional Food Association) since 2006 when NPA was still known as NNFA, as its Vice President of Scientific and Regulatory Affairs. For approximately one year, Dr. Fabricant was also the Acting Executive Director/CEO of the NPA; hence, he held second and first executive positions

at NPA. The NPA is the oldest trade association for the dietary supplement/natural foods industry. It has been in existence over sixty years and is well known and well respected by the agency and many members of Congress. The NNFA played a major role in the drafting and passage of the 1994 Dietary Supplement Health and Education Act (DSHEA). Over the years, the role of the NNFA vis-à-vis the FDA, more often than not, has been forceful advocacy by the industry (from the supplier through retail end of the chain) as well as the critical agent in organizing millions of consumers in the effort to preserve the right of access to a broad range of supplements, in advancing the interests of the supplement industry, and in lobbying Congress. As you know, the industry's relationship with the FDA has been fraught with problems, even after Congress defined dietary supplements as a product category.

DSHEA itself is the *sine qua non* example of pro-industry advocacy and activism. Prior to DSHEA's passage, the agency intended to regulate supplements as unapproved food additives and which would have eviscerated the industry. The agency's exemplar nutrient for their regulatory schema (or "rationale" if you will) was carnitine. If one needed carnitine, it was a drug, and if one did not need it, then selling it would be deemed fraud and the consumer barred from access by forbidding companies to manufacture or sell it. The historic struggle against this arbitrary agenda was enormous, and millions of Americans rallied to the cause and saved their right to access to dietary supplements. Unfortunately, this struggle continues to the present day: In a reprise, Jarrow anticipates another mass response from the American people against the proposed New Dietary Ingredient (NDI) guidelines, which are little more than the "Unapproved Food Additive" tactic by other means.

During the DSHEA fight in 1993 and 1994, many confidences were exchanged among manufacturers, retailers, attorneys, and other trade associations, particularly via the NNFA and the Council for Responsible Nutrition (CRN). This process of confidential dialogue must necessarily continue: The agency recently promulgated draft guidelines for NDIs that in virtually every regard are contrary to the spirit, if not the letter, of DSHEA, especially Sections 4 and 8 of the statute. Accordingly, once again, companies and the public, and food and drug attorneys who represent the industry need to be able to exchange information and legal analyses and strategies freely without concern that the confidentiality and integrity of the information might be compromised by some future errant trade association executive -- such as Dr. Fabricant -- in concert with the agency charged with regulating. This is exactly what has occurred with the appointment of Dr. Fabricant as FDA's Director of Dietary Supplement Programs.

It is categorically impermissible for a regulatory agency to recruit its top compliance and regulatory officers from the top executive management of trade associations of the very same industry that the agency regulates. What the agency has done is a direct attack on the very concept and role of a trade association. The hiring of Dr. Fabricant from the NPA is not at all analogous to hiring an executive from a private company, or to private companies recruiting from competitors, or to industry hiring a former regulator. Trade associations have very particular fiduciary duties to represent the interests of their members, particularly when there is a regulatory agency involved; and it is a relationship of trust that often includes legal strategy and analysis – in essence, *privileged* information – in conjunction with sensitive company matters disclosed in confidence and analogous to the attorney-client relationship. **Indeed, the offer and acceptance of this employment resulted**

in Dr. Fabricant not only abrogating his previous fiduciary position, but actually violating the previous attorney-client relationship since he was present at and engaged in numerous conversations and exchanges of various correspondences with the NPA's attorneys. Indeed, Dr. Fabricant was privy to all of these forms of highly confidential knowledge and information. Thus, what the FDA has done threatens to undermine the ability of trade associations and the dietary supplement industry they represent, and advocate for, to function together.

The situation evokes the heuristic principle of the "Is-Ought Fallacy," that if it *is* – Dr. Fabricant being hired from the NPA to be Director of Dietary Supplement Programs for the FDA -- then somehow it is acceptable, or even, *ought* to be. Nothing can be further from the truth.

Dr. Fabricant's appointment has sent a ripple of anxiety through our industry, especially at the time of the Comment period for the NDI Draft Guidelines, which are not simply overly burdensome to the industry, but also in the opinion of many – including most respected food and drug attorneys such as Scott Bass and Wes Siegner – in essence dismantle DSHEA.

At such a critical juncture, given the history of FDA's apparent willingness to recruit from the leading trade association responding to the Draft Guidelines, how are members to believe or trust the employees and executives of their trade association? (Or, for that matter, that of any other like regulated industry such as the pharmaceutical trade associations.) Is the person to whom an industry member is speaking working at cross-purposes because he or she intends to move to the FDA? Or might in the future? The very purpose of trade associations in this – and any other -- highly regulated industry is gravely threatened; and FDA has clearly crossed the line by intruding into the right of businesses to associate in their own behalf and interests and be represented to the regulatory agency by a trade association. Moreover, the agency has seriously eroded industry as well as public confidence in the ability of the agency to recognize impropriety. The feedback I have received from numerous members of this industry has been virtually unanimous. They are frankly dismayed at the agency's and Dr. Fabricant's conduct. Notwithstanding the foregoing, ironically, Jarrow has no doubt that the agency would not consider for a moment hiring the science director and former acting executive director/ CEO of, for example, the Drug Manufacturers' Association to be its director of any "Drug Manufacturing Programs." The hue and cry would be deafening. The appointment of Dr. Fabricant as Director of Dietary Supplement Programs is equally problematic and ethically compromised.

III. FURTHER CONFLICTS OF INTEREST

The agency has a clear conflict of interest in this hiring if only because it undermines the agency's attempt to have the industry's members see themselves as "stakeholders" rather than vassals and serfs. To be a stakeholder, one needs a certain arm's length independence and trust, which is being defenestrated by this hiring. The long-term effect of Dr. Fabricant's tenure, or "reign," will be profoundly chilling on supplement industry members, which is already being felt on the Comments to the NDI Draft Guidance as described below. Having worked both sides, Dr. Fabricant will be in the position of expounding that he may be presumed to hold a "superior overview" – no matter how disingenuous or irrelevant the claim is at this point. The agency has tilted the playing field in its favor by this hiring.

As for Dr. Fabricant himself, this is a dismaying conflict of interest. In an interview conducted by Angela Cortez, a former New Hope Natural Media editor and published in *Natural Foods Merchandiser,* 9/25/2009, after he became acting director of the NPA, Dr. Fabricant appears to pledge fealty to the industry, promising to lead in protecting DSHEA against any legislative attempt to undermine the Act. In the interview, Dr. Fabricant states, inter alia:

> We have our critics on Capitol Hill that want to see *additional regulation*. As we have always done, we are standing watch and working diligently to advocate for the industry as well as thwart *any potential legislative threats* to the Dietary Supplement Health and Education Act. [Emphasis added.]
>
> With the challenges ahead, we as an industry have to be involved in the political process, which means that it is more important than ever to belong to a trade association, meet with your elected officials, and donate to fundraisers and political action committees. There is a saying in D.C. that if you're not at the table you might be on the table….

In retrospect, there is too much *chutzpah* in the remarks to describe them as merely painfully ironic. The once-proclaimed "industry advocate" – after all, he was *Acting Executive Director/CEO of the NPA(!) as well VP) –* is now in charge of this very activity, i.e., additional regulation of the industry in terms of severely limiting any new dietary supplements that may be marketed and sold. One can only be left incredulous. Dr. Fabricant is now leading the process to erect unnecessarily high barriers to the introduction, not just of new ingredients, but even mere reformulation of established ingredients. This is the very type of regulation he had vowed to lead to oppose. The conflicts of interest of Dr. Fabricant are self-apparent, as is the hypocrisy of the conflicting roles. Any objective observer could not help but be dismayed at both Dr. Fabricant and the agency. It is arch hubris for Dr. Fabricant to declaim the importance of the role of the trade association – from its pulpit! -- in one permutation and then to become its adversary in another.

IV. FORTHCOMING FREEDOM OF INFORMATION ACT (FOIA) REQUEST

Jarrow Formulas will be filing a formal FOIA to the FDA to produce all documents in all media and forms available responsive to the following Requests:

1. When did the FDA contact Dr. Fabricant or vice versa?

2. Over what period of time did the employment negotiations between the agency and Dr. Fabricant occur?

3. Were there any discussions of industry reaction or conflicts of interest?

4. Did the agency publish the position's availability?

5. How many applicants were there?

6. Were any other applicants considered after Dr. Fabricant's application?

Pursuant to the FOIA statute, Jarrow Formulas will formally request that any and all documents regarding these questions be produced at the earliest possible date as Time is of the Essence given the limited Comment Period available to the industry to respond to the NDI Draft Guidelines.

V. THE HIRING PROCESS FOR DR. FABRICANT: UNANSWERED QUESTIONS

It is of great concern to Jarrow that the NPA knew nothing of Dr. Fabricant's plans or intentions until he handed John Gay, NPA's Executive Director, his two-week notice letter of resignation. Unfortunately, Dr. Fabricant was not debriefed on any of these crucial matters. I suspect that the principals of the NPA may have been too shocked to know how to respond at the time. (This is personal surmise on my part.) The fact is, Dr. Fabricant should have resigned before he even approached the FDA, certainly as soon as negotiations began. This would not have resolved the overall conflicts but timely resignation certainly would have lessened them by one.

Further, the FDA itself had a duty to instruct Dr. Fabricant to immediately disclose to the NPA that he was interviewing with the agency for the position of Director of Dietary Supplement Programs. That failure alone disqualifies Dr. Fabricant from any further responsibilities in dealing with dietary supplements regulations. The FDA must incur the penalty of its failure to inform the NPA and the trade industry of its intention to hire Dr. Fabricant.

While employed as the #2 – and #1 – executive of the NPA, Dr. Fabricant certainly had his friends as well as those with whom he had less than cordial relations. FDA had an obligation to assume that Dr. Fabricant had simply been too close for too long with too much of the industry for him to be presumed to be objective and arm's length. This is not an aspersion on Dr. Fabricant but a normative standard for any competent Human Resources Department in such a sensitive matter

This hiring does have a "resume problem" in that Dr. Fabricant, when he was Acting Executive Director/CEO of the NPA, was hoping to be appointed by the NPA's board permanently to that position. The undersigned has it on good authority that Dr. Fabricant was disaffected when he was passed over for this promotion. Subsequent employment by FDA in these circumstances would be expected to be less than auspicious for the industry. Jarrow does not believe that future discussions between the agency and the NPA, in particular, will be as constructive as they would otherwise be. An underlying awkwardness is unavoidable – and undeniable. In addition, Dr. Fabricant's relationship with the rest of the industry will remain discomfited, to say the least. The current situation is detrimental to the agency's relationship with the "stakeholders."

VI. DR. FABRICANT HAS ALREADY DEMONSTRATED PRE-JUDGMENT TOWARD THE SUPPLEMENT INDUSTRY RE NDI DRAFT GUIDANCE

The recent publication of the NDI Draft Guidelines (July 1), and Dr. Fabricant's position of responsibility for this important regulation highlight the conflict of interest and the impropriety of his appointment. For example, in mid-July, a food and drug attorney was asking questions to a CFSAN official about the NDI Draft Guidelines. In the middle of the conversation, the attorney was suddenly informed by the official that he (the official) had been instructed that the division should not answer questions or discuss the NDI draft guidelines, but instead should direct callers to send in written comments or questions. (So much for "stakeholders" status.) The attorney asked whether this instruction had come from Dr. Fabricant and the hesitant response was Yes, that it had been at Dr. Fabricant's direction. Jarrow considers this to be tantamount to a gag order and the sort of managerial overreach one would expect from someone recruited from the opposing camp. Gag orders over draft guidelines are unacceptable!

On July 11, the NPA held a webinar in which Scott Bass, Esq., counsel for NPA, and Dr. Fabricant "engaged" over the draft NDI guidelines – that is, when Dr. Fabricant chose to engage and not obfuscate or otherwise convey views that lead Jarrow to believe that the FDA's newly minted Director of Dietary Supplement Programs intends to enforce the harshest possible regulatory regime as to NDIs. (See http://www.jarrow.com/eMarketing/ndi-webinar.html to listen to this webinar). Dr. Fabricant's seemingly reasonable tone of voice should not distract from what were legally unreasonable and scientifically baseless conclusions. Jarrow believes that Dr. Fabricant displayed a lack of concern for, if not callousness toward, the real shock with which this unexpectedly severe Draft Guidance was received. His repeated comment that this NDI Draft Guidance should be "no surprise" implies that it is not only a continuation of past FDA policy but also that Dr. Fabricant exhibited no appreciation or understanding for the industry he had previously worked for and represented – much less any self-awareness of the stark contrast to the averments and commitments he had once made. Not only were commentators and webinar participants shocked at Dr. Fabricant's apparent cavalier attitude, but the industry adamantly disagrees with Dr. Fabricant and the agency that the Draft Guidelines are consistent with DSHEA or otherwise justified.

Unsurprisingly for this "convert," from industry advocate to industry regulator, Dr. Fabricant displayed an anticipatory relish for the task of enforcing this particular version of the Guidance which was unsavory. It bordered on the illegal given that the agency is several months away from issuing the Final Guidance. Dr. Fabricant's comments demonstrated a total lack of awareness or concern that *by law* the agency must rigorously review industry and public comment and take them into *serious consideration* before any final Guidance is issued. Dr. Fabricant has too many years of industry experience with Proposed Rules and Comments to be presumed not to know otherwise. His performance at the webinar has been described as cold, condescending, and at times, inappropriately sarcastic. I certainly found him indifferent to the enormous, unnecessary burden, cost and loss of business opportunity that was being imposed on the industry, and the negative effect on consumers: The Draft Guidance in its current form would make most innovative, new supplements – including simple reformulations – cost prohibitive. (It also appears that its technological prohibitions, if applied today to substances such as coenzyme Q-10 would bar introduction of such ingredients!) DSHEA is predicated on the health of the American people, not just the economic welfare of the industry. This is despite the fact that the reincarnated Dr. Fabricant seemed oblivious to what gave impetus to the Act.

As to Dr. Fabricant's apparent unconcern for the legal rulemaking process spelled out in the U.S. statute known as the Administrative Procedure Act (APA): As you know, the APA mandates that federal agencies develop and promulgate new regulations using the procedure known as "Notice and Comment" rulemaking. A notice of a Proposed Rule is published in the Federal Register; then the affected industry and other stakeholders have the opportunity to send formal Comments to the agency; and then the agency—by law—is directed to consider seriously those comments in revising the Proposed Rule into the Final Rule, or binding regulation. The FDA's Draft Guidance on NDIs was published on July 5, with a 90-day comment period. Thus, the industry and the agency are now only at the beginning of the comment period, which closes on October 3. It is entirely too premature to speak of the NDI Draft Guidance as if it were already a binding regulation, yet this was precisely the tenor and tone of Dr. Fabricant's presentation on July 11.

During Dr. Fabricant's presentation (in the first section of the webinar), he repeatedly implied that the NDI Draft Guidance would also be the FDA's Final Guidance: that it was a *fait accompli*. He used the phrasing "*If* the Guidelines are revised." This was a strong implication that the Guidelines may well not be revised at all—in response to industry comments—which would violate the APA's set procedure. The industry representative during the webinar was Scott Bass, Esq., who stated a few times (correctly under the law) "**when** the *Draft* Guidelines are revised." Dr. Fabricant again repeated, "*If* they are revised." (Please see link herein.) The import of this distinction is huge: If an agency does not carefully consider the Comments in its preparation of a Final Rule, then that agency is vulnerable to a lawsuit on the grounds that the rulemaking in question was arbitrary and capricious.

Moreover, during this same webinar about the NDI Draft Guidance, Dr. Fabricant actually—and astonishingly—even tried to dictate what type of Comment should be filed by the industry. He stated that the FDA was "not interested" in "vague, general criticisms" of the Guidance. Rather, he said, Comments should focus on specific questions about particular ingredients, that FDA wants to know if any part of the Guidance is ambiguous: "Tell us what needs to be clearer," he said. Again, this unmistakably implies that only the application of the Guidance to certain ingredients is at issue, that for the standards which form the body of the document the Draft Guidance is somehow already Final (in its basic form, structure, and direction), and will not be changed—even based on legitimate critiques by the industry.

Nevertheless, Jarrow Formulas, Inc. respectfully informs the agency that, despite Dr. Fabricant's admonishment, the company indeed intends to file extensive Comments—which will actually be "critical" in all senses of that word -- detailing that the Draft NDI Guidance contravenes both Section 4 and Section 8 of DSHEA.

Unfortunately, the remarks of Dr. Fabricant (in the context of a webinar intended to "teach" the industry about the NDI Guidance) reveals a prejudice (literally pre-judging) about the yet-to-be received comments! The FDA committee (now headed by Dr. Fabricant) charged with producing the Final NDI Guidance should begin judging the Comments only after October 3, when the comment period closes.

While Dr. Fabricant triumphantly faulted the industry for not having submitted anywhere near the NDI Notifications he believes it should have, he evinced no self-awareness that the agency's delay of 17(!) years in issuing an NDI Guidance in essence ratified the status quo and implied that there are no major safety problems needing the Draft Guidance's Draconian prescriptions to cure. Dr. Fabricant essentially placed all blame and responsibility on the industry rather than recognizing that the agency itself, given the views he espoused, had failed to enforce what it now asserts was the supposed statutory standard. In truth, all the NDI Draft Guidance does is threaten devastating economic consequences for the industry and wholesale denial of health products to the public. To that end, Dr. Fabricant's version of the NDI Guidance is that companies must have "proof" -- 17 years of record retention -- in order to "prove" that each and every formula being sold currently is "pre-DSHEA."

VII. DURING NPA's WEBINAR, DR. FABRICANT MISCHARACTERIZED THE LAW AND SKEWED THE FACTS RE. SAFETY OF SUPPLEMENTS

In the NPA webinar, Dr. Fabricant repeated 3 or 4 times that the NDI Guidance had to be extremely rigorous in the context of FDA's mission to protect the "public safety" and to ensure "preventive controls" for safety. Here, he seems to have "forgotten" that DSHEA was based on the presumption of the safety of dietary supplements, and the history of the industry validates this as fact. As the legislative history of DSHEA, specifically Sections 4 and 8, shows, all supplements on the market pre-DSHEA were presumed to be safe by Congress. Dietary supplements—both traditional and newer, post-DSHEA ingredients—have a stellar safety record and profile. Per FDA's own records and analysis, barely one death per year can be attributed to a supplement. Consider the contrast with foods, where 5,000 deaths per year are caused by food poisoning, and with OTC drugs, where 500 deaths per year are caused by NSAIDS. **Why would a man who was chief of a supplement trade association either be oblivious to or attempt to obfuscate these facts?**

As evidenced by his July 11 remarks at the NPA webinar, Dr. Fabricant clearly has ignored FDA's own prior recommendations regarding supplements as well! First, in his repetition of dietary supplements as a significant safety issue, Dr. Fabricant took no cognizance of FDA's outright rejection of many of the suppositions in a 2009 GAO report that had recommended further oversight of supplements by the agency.

In May 2009, Jarrow Formulas filed an extensive Freedom of Information Act Request (FOIA) to FDA, seeking information on the communications between FDA and GAO that led to GAO's conclusions about supplement regulation. In response to that FOIA Request, FDA produced a January 22, 2009 report [FDA's General Comments to the U.S. Government Accountability Office's (GAO) Draft Report Entitled: "Dietary Supplements: FDA Should Take Further Action to Improve Oversight and Consumer Understanding" (GAO-09-250)] that, in sum:

1. Dismissed GAO's notions that registration of all supplement firms, as well as information on the identity and composition of the products they market actually would enhance supplement safety.

2. Rejected GAO's recommendation that supplement manufacturers report all adverse events, as such a policy would clog the system and prevent FDA from proper focus on serious adverse events.

3. In no way suggested or endorsed a revision of the Food, Drug & Cosmetic Act with respect to the "New Dietary Ingredient" provisions of the Act (a revision that Dr. Fabricant arguably is trying to achieve by regulation!).

Stunningly, GAO did not even take the time to review or consider FDA's unambiguous rejections above—which overall argue for the safety of supplements, not requiring improved "oversight." Again, FDA's Chief of Staff sent its comments to GAO's "draft" recommendations on January 22, 2009. Exactly one week later—January 29, 2009--GAO issued its final report, clearly without any time to consider or incorporate any FDA or third party input or objections.

The FDA's January 22, 2009 memo expresses two relevant concerns: That the agency had limited resources to respond to every petty non-serious non-event (my term for what the GAO proposed the FDA undertake; and apparently the FDA memo concurs with this sentiment), and second, ***and most salient hereto: The FDA rejected the GAO's recommendation of registration of dietary supplements or premarket approval. Apparently, Dr. Fabricant also does not read CFSAN's own memos—to the GAO!***

It is painfully clear that the drafters of the NDI Draft Guidelines intend to achieve this daunting and completely unnecessary registration requirement by other heavy-handed means. The Congress has rejected premarket approval and registration of dietary supplements—most recently in the withdrawal of the core provisions of Sen. McCain's bill on Supplement Safety in Spring 2010.

Second, Dr. Fabricant clearly ignores the laudable safety record of dietary supplements. This omission-- indeed skewing of evidence to the contrary-- is pathetically ironic, given his background as a scientist and a former supplement industry executive. For example, documents produced as a result of a 2006 FOIA request by Jarrow Formulas evidence the remarkable record of supplement safety vis-à-vis drugs. This FOIA request was motivated by a member of Congress making off-hand remarks at a press conference that "Supplements are killing people." So in this FOIA the main question for the FDA was: How many non-ephedra deaths were demonstrably *caused by* dietary supplements during the first 12 years of DSHEA? The answer was: likely, not even one.

In stark contrast to more than 400,000 adverse event reports for drugs, there were only 129 serious adverse event reports for dietary supplements in over 12 years—only 6 of which were deaths, that the FDA, in its FOIA response, found to be "biologically plausible," but not caused by the supplements. The FDA determined that all 129 of the supplement AERs would require further analysis as to actual cause, as they often corresponded with prescription medications and/or pre-existing conditions. In fact, close review of those incidents revealed that some of the products ingested were not truly supplements (but rather were foods, one of which probably caused, pre-2006, a fatal allergic reaction). Other of the six cases included concomitant use of drugs, serious medical history, etc., indeed, similar to the "confounding" factors that complicated the death of the Oriole's

pitcher, Steven Bechler, which was blamed on [overuse of] an Ephedra supplement. Significantly, FDA could not substantiate even one death "caused by" a non-Ephedra supplement in over 12 years!

Dr. Fabricant argued disingenuously as well. He put forth arguments that in his previous position he would have been expected to rebut with facts and science. His reference to ephedra was out of context, as it is well known that it was a combination of factors that led to its virtual ban: Combining it with caffeine and constant misuse (overdosing) by consumers who ignored the usage directions.

By contrast, true to the Congressional forecast that DSHEA assures consumers "freedom of choice while guaranteeing that unsafe products can be removed quickly from the market" (Senate record, October 7, 1994), relatively few injuries or deaths can be attributed directly to supplements, most of which resulted from gross over-use contrary to explicit label directions. This certainly was the case with events associated with ephedra, with excessive consumption by consumers in attempts to lose 20 pounds in a week or throw a football farther! Dr. Fabricant should know better than to raise the old bugaboo about ephedra (routinely resurrected by misinformed opponents of the supplement industry) and for that matter, steroids, which are drugs, not supplements!

Yet, his other prime example for why tight safety constraints on new dietary ingredients are needed was, again, body building "supplements" that are spiked with hormones or drugs. Steroids and hormones are not new dietary ingredients; they are not even *dietary* ingredients. To somehow shift the blame for steroid use by athletes seeking fame and (incredible) fortune to the reputable, science-driven supplement industry is an unconscionable ploy. To combat illegal steroid use, one need only look to enforce the Anabolic Steroid Control Act of 2004, and leave supplements alone.

Dr. Fabricant also disingenuously referred to the "fact" that the agency had conducted more recalls than they had received NDI notifications. Dr. Fabricant misled by design: The "recalls" were primarily in one area: "Athletic (Body Building) Supplements" from the same small number of usual suspects. In his previous incarnation, Dr. Fabricant would have rebutted such a (mis)representation if the agency had made it. In fact, he did exactly that when testifying before a subcommittee of former senator Arlen Specter. Is Dr. Fabricant's memory really so short?

What I was particularly struck by was Dr. Fabricant's fabricated concern for "safety." He seems to have "forgotten" that DSHEA was based on the presumption of the safety of dietary supplements and the history of the industry validates this as fact. In fact, the Adverse Event Reporting Act has demonstrated the overwhelming safety of supplements, much to the disappointment of the industry's detractors who assumed it would help "nail" the industry for them. The reports are overwhelmingly non-events and the complaints of demonstrable hypochondriacs or people who are actually self-misdiagnosing drug and illness events. That is exactly why the industry, including Jarrow, strenuously supported passage of the AER Act: To put the lie to exactly the sort of balderdash being espoused by the reinvented Dr. Fabricant. The overall low number of any types of events and the extremely few arguably serious events means that the AER bill has exposed the posturing and hysteria of DSHEA's self-anointed opponents. Time has quickly proven the industry resoundingly safe.

In this regard, in his July 11 webinar remarks, Dr. Fabricant obstinately insisted on the position that formulas containing well-established, perfectly safe ingredients need a 75-day NDIN when they undergo even the most minor formula changes. He showed no willingness to even consider the absurdity or the horrendously burdensome nature of a procedure that Congress never intended and will outrage the public when it finds out what the agency is up to, especially when the economy is stressed and the public angered at government's inability to reign in profligate spending and gratuitous overregulation.

Dr. Fabricant exhibited indifference over whether the agency could even handle the number (over 55,000!) and sort of submissions that he was so blasé about. In his previous position, Dr. Fabricant would have been aware of certain rejections by the agency of NDINs for reasons of "uncertain safety" for formulations containing nothing more than pre-DSHEA ("grandfathered") ingredients. The rejections were arbitrary, without foundation in fact, contrary to the doctrine of "history of safe use," and scientifically pure poppycock. During the webinar Dr. Fabricant dismissed the notion that unreasonable rejections could possibly have occurred or ever would. He held forth that only vital, if only simple, pro forma, information had been omitted and that the agency was actually attempting to facilitate notifying companies. Yet, by his own numbers, if one did the math, only 17% of submissions were "acknowledged" – meaning the ingredient or formulation would be allowed on the market. (While the actual number of NDINs "acknowledged" may have been 25%, the numbers given at the seminar yield a 17% passing rate.) The industry-crusader -turned regulatory-champion glossed over this salient low yield.

It was in this context of Dr. Fabricant trying to rationalize the excessive and gratuitous requirements in the Draft NDI Guidance and a slew of arbitrary and Kafkaesque rejections that he repeated his statement that he is (now) in the "safety business." (***He wasn't before?!)*** This assertion was disingenuous, thoroughly condescending and an insult to the intelligence – as well as to his previous employers and those he once spoke for.

As a relevant aside, Jarrow is also concerned that since the only real reason for the July 11 webinar was the participation of Dr. Fabricant, he allowed himself to be the occasion for the NPA to charge $150 to $300 (member versus non-member fees) to log onto the event. Since when do FDA officials allow themselves to appear as the sole attraction when the public or regulated industry must pay substantial fees to hear them? Again, this blurring of the demarcation between the agency and a trade association is impermissible.

The placement of Dr. Fabricant in this position can only be seen as a disregard for the independence and integrity of the regulated industry and its trade association relationships and the industry's unfettered right to associate, strategize, lobby Congress and dialogue with the agency itself. The agency should now realize how problematic and inappropriate is the hiring of a former NPA high level executive as a high level regulator.

VIII. THE FDA HAS SET AN HISTORIC AND DANGEROUS PRECEDENT IN HIRING A TOP TRADE ASSOCIATION EXECUTIVE TO BE THE DIRECTOR OF PROGRAMS REGULATING THE INDUSTRY HE ONCE REPRESENTED BEFORE THE AGENCY AND CONGRESS

As the principal of Jarrow, I deliberated long and thoughtfully in the process of drafting this letter. While there were several occasions when my interactions with Dr. Fabricant left much to be desired, there is absolutely no personal motivation for writing this letter other than my three-decades long commitment to my industry, my companies and my customers – businesses and consumers alike. I approach this letter with the same concern I have for producing quality formulas and underwriting valuable and important scientific research. I am also the founder, past two-term president and current Board member of the International Probiotic Association (the IPA), and an honorary lifetime member of the Oxygen Club of California, a scientific society dedicated to redox regulation and energy metabolism research. Jarrow funds the Jarrow Formulas-Oxygen Club of California Life Sciences Prize. (The first recipient discovered Tumor Necrosis Factor-alpha and the next recognition will be the co-discoverers of Nuclear-Related Factor 2, NRF2.) It is a simple fact that having to constantly take time to work in defense of my business and the right of the American people to have access to dietary supplements and to protect the ability of the industry to develop new technology is more than frustrating and distracting.

I am not interested in rehashing my past relationship with Dr. Fabricant other than to state that Jarrow requests that he recuse himself from any matter concerning my companies. Suffice it to state that this letter alone should be reason enough.

The concerns expressed in this letter are widely shared throughout the industry. It seems reasonable to conclude that the agency and Dr. Fabricant, consciously or otherwise, relied on the inherent intimidation factor: The combination of regulatory agency and former trade association executive/scientist could be presumed to be so patently intimidating that no company would dare to object to this clearly compromised arrangement. The industry, however, has been underestimated and Jarrow has undertaken the task of conveying the message: FDA's hiring of a former trade association executive to regulate the industry he once represented to the self-same agency is an historic and dangerous precedent; thus, on behalf of the industry, Jarrow serves this unswerving, uncompromising protest.

Dr. Fabricant has numerous irreconcilable conflicts of interest. Thus, the agency needs to ask itself the following two questions: If Dr. Fabricant's position were one of Senatorial Advice and Consent, would the nomination be approved? I think not. The questioning would uncover too many embarrassing and improper contradictions and conflicts. Second, if Congress members inquire into this hiring, how is the agency going to justify not just this particular appointment, but also whether what is arguably the most important regulatory agency of government is setting an unethical, ill-considered and unwise precedent. How would the agency explain this type of hiring to the Committee on Oversight and Government Reform, as an example?

IX. CONCLUSION

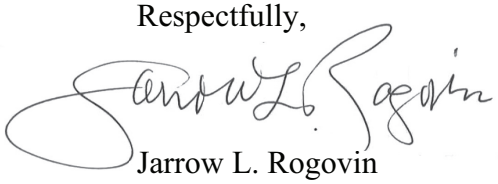
For the foregoing reasons, Dr. Fabricant is encumbered in his current position with irremediable conflicts of interests. Accordingly, Jarrow Formulas respectfully requests – nay, urges – the removal of Dr. Fabricant from any responsibilities involving the dietary supplement industry, an industry to which he has betrayed his previous fiduciary trust. Dr. Fabricant's talents can be

utilized elsewhere in the agency, but not concerning the regulation of dietary supplements. In particular, Dr. Fabricant should not be involved any further in the review of Comments on the NDI Draft Guidance nor in determining the agency's response, revision and Final Guidance. As aforestated, the question of Dr. Fabricant's involvement in implementation and enforcement is completely unacceptable to the industry.

Failure by the agency to undertake expeditiously the appropriate action will seriously undermine its efforts to improve its relationship with the regulated industry. Retaining Dr. Fabricant as the Director of Dietary Supplement Programs will leave in place an official who, in the eyes of the affected industry, fundamentally and simply lacks legitimacy or credibility. In the long run, it will undoubtedly redound to the detriment of the agency.

Jarrow would welcome the opportunity to assemble a group from the dietary supplement industry to discuss these issues and concerns further in an in-person meeting with you and/or other appropriate officials of the FDA. Jarrow does not believe a meeting primarily with Dr. Fabricant would resolve anything as the conflicts are irresolvable. Thank you in advance for considering this suggestion and for your serious consideration of the points in this letter.

Respectfully,



Jarrow L. Rogovin
President and Chairman of the Board,
Jarrow Formulas, Inc.
Chairman of the Board, Jarrow Industries, Inc.

cc: All Members, Senate of the U.S.
All Members, House of Representatives of the U.S.
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Daniel Fabricant, Ph.D., CFSAN, FDA
John Gay, Executive Director, Natural Products Association
Steve Mister, Executive Director, Council for Responsible Nutrition
Mark Blumenthal, Founder/President, American Botanical Council
Ioannis Misopoulos, Executive Director, International Probiotic Association
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