December 1, 2011

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Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2011-D-0376, "Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues"

Dear Commissioner Hamburg,

The National Health Federation (NHF) – the World's oldest health-freedom organization with thousands of members who are consumers and/or with the industry – respectfully submits the following comments on the above-referenced Draft Guidance for Industry:

1. Withdraw Draft Guidance for Industry – Overall Comment. Numerous problems are evident with the Food and Drug Administration's (FDA's) draft Guidance document, as detailed below, and in other comments submitted to your Agency. The Dietary Supplement Health and Education Act of 1994 (DSHEA), which passage was aided in large part by our organization, dictates the parameters within which the FDA may operate with respect to dietary supplements. In almost every important respect, your Agency has exceeded those parameters and, as such, the draft Guidance is null and void, and of no legal effect. The law is clear that any Federal Agency may only operate within the legal boundaries set forth by Congress, the very authority that created the Agency in the first place. Your Agency may not overstep its bounds by engaging in rule-making through Guidance documents.

2. Illegal Extension of Control Over NDIs. New Dietary Ingredients refer to just that – ingredients. Not products. Yet, the FDA, through this draft Guidance, would change the law dramatically by requiring manufacturers to submit for FDA approval every product that contains an NDI or whenever a formula is changed, or a new technology, no matter how minor, is used. As such, the FDA Guidance document disregards DSHEA Section 413 [21 USC §350b], which says that an NDI submission is not required if "there is a history of use or other evidence of safety" supporting its inclusion, use, and marketing prior to October 15, 1994." Rather, the Guidance document treats NDI submissions as product-specific rather than ingredient-specific, which contravenes the not only the letter but the spirit of the law.

3. Unnecessarily Costly with No Corresponding Benefit. The implementation of the directives found in the draft Guidance document would impose huge costs upon the industry. These

costs would then be largely passed onto the shoulders of consumers, effectively pricing most dietary supplements out of the reach of consumers while eliminating those supplements that manufacturers would find were not marketable because of their high prices.

The FDA's proposed Guidance would require all dietary ingredients introduced into the marketplace from October 15, 1994 onward to undergo drug-like safety testing prior to marketing. The tests could cost millions of dollars per each "new" ingredient, and that includes each variation on that ingredient too. These requirements would not make supplements any safer than they are today and would require supplement makers to lay aside 20 years of profits to conduct the tests. To make matters worse, tens of thousands of workers could lose their jobs as the supplement industry would be forced to remove products from store shelves.

Alarmingly, every company would have to file its own NDI notification for the exact same new ingredient that some other company may have already tested as safe, and already received FDA clearance for, with its own successful NDI notification. This duplicative approach is so obviously unnecessary that it can only be truly seen as evidence of intent to kill this industry.

Too, while many of these dietary supplements have been on the market for over a decade without reported deaths or significant side effects, the FDA's proposed new Guidance appears to be nothing more than an expensive paperwork exercise intended to eradicate many safe products from the marketplace.

4. Supplements are Exceedingly Safe; These Controls Are Unnecessary. As the NHF has been explaining for years, dietary supplements are ***exceptionally*** safe. Statistically, a person is more likely to die from a bee sting or a lightning strike than he or she is from taking dietary supplements.

Dr. Andrew Saul confirmed this viewpoint when he cogently wrote, "The 2003 Annual Report of the American Association of Poison Control Centers Toxic Exposures Surveillance System states that there have been only two deaths allegedly caused by vitamins. [*See American Journal of Emergency Medicine*, Vol. 22, No. 5, September 2004; http://www.aapcc.org/Annual%20Reports/03report/Annual%20Report%202003.pdf.] Almost half of all Americans take nutritional supplements every day, some 145,000,000 individual doses daily, for a total of over 53 billion doses annually. And from that, two alleged deaths? That is a product safety record without equal." More recent figures simply confirm this safety record for supplements.

Compare this to pharmaceutical drugs, Dr. Saul continued, which even when properly prescribed and taken as directed, kill some 106,000 Americans each and every year. At over 2,000 deaths ***each week*** (and some doctors estimate the toll to be much higher), that is quite a death rate. (*See* Leape LL, "Error in Medicine," *Journal of the American Medical Association*, 1994, 272:23 at 1851; Leape LL, "Institute of Medicine Medical Error Figures are not Exaggerated," *JAMA*, 2000 Jul, 5;284(1):95-7.) Clearly, supplements and drugs are not even in the same class. And they should not be treated in the same way either, which is exactly what the draft FDA Guidance document wants to do for "new" dietary ingredients.

To impose such a high regulatory burden both in cost and in health on a market segment that is exceedingly safe is regulatory overkill of the highest order. The costs do not justify the benefits; and the hidden costs are quite high indeed as ordinary supplements will be priced beyond the reach of consumers, whose health will suffer and decline as a result. In fact, many more individuals will be harmed and killed as a result of imposition of the FDA's draft Guidance than if the industry were left subject to existing laws, rules, and regulations, which have already shown that they adequately safeguard the health of the public.

5. Violates APA. By law, Federal regulations must be created through proper notice and procedure. The FDA's effort here to create completely new regulatory requirements through this Guidance document – above and beyond existing law and regulation – violates the Administrative Procedure Act (APA). This agency over-reach is improper and alone warrants the immediate withdrawal of the draft Guidance.

6. Violates Congressional Intent. By imposing unnecessary and costly burdens upon manufacturers and other members of the industry, the FDA's draft Guidance document ignores the clear intent of Congress when passing DSHEA that "the Federal Government shall not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers" and that "the right of access of consumers to safe dietary supplements is necessary in order to promote wellness."

Madame Commissioner, this draft Guidance does exactly that, it thwarts consumer access to proven safe dietary supplements – supplements that are already safer than their opposite numbers in the drug regulatory regime administered by your Agency.

For all of the above reasons, and many more, withdraw this draft Guidance, create one in line with the law, existing regulations, and Reality, and work instead towards improving Americans' health and wellness by advancing the current use of dietary supplements.

Respectfully submitted,

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