FDA Draft Guidance for Supplement Industry
The MLM Sky is Still Not Falling!

By Len Clements © 2011

Back in the early 90s it was the mainstream media that was supposedly colluding to destroy the MLM industry, ostensibly to protect American consumers, but really because we were a growing force that, if not stopped, was going to cost them billions in advertising revenue. What's going to happen, the Chicken Littles' would ask rhetorically, when this word-of-mouth based juggernaut surpasses the franchise industry and accounts for more than one-third of all the goods and services sold in this country – "by the end of the 90s"? The Wall Street Journal, USA Today, Forbes Magazine, 60 Minutes, Dateline – they all exist on advertising dollars! They must destroy this person-to-person referral scheme and end this plague of profit pilfering. That was their real motive, we were told. It wasn't the FTC, FDA or SEC we should be worried about. It was ABC, NBC and CBS!

In reality, USA Today, Newsweek and ABC's "Nightline" all published negative, accusatory reports about Nu Skin in 1991 because they were over-hyping their opportunity and front loading new recruits with thousands of dollars of inventory. ABC's "20/20" aired a scathing segment on Bill Gould and his company Equinox in 1996 because it was a flaming pyramid scheme. News reports blasting Jewelway, Destiny Telecom, FundAmerica, and many others were also well deserved. But then, Success magazine had already discovered how to get money from MLMers even if we don't buy display ads. Just write something nice about us, which they did in March of 1992. To a fault, actually, with the cover of that issue emblazoned with "We Create Millionaires", along with "Their Eager Disciples Build Overnight Empires". Yep, it really said "overnight". Nevertheless, that issue of Success sold out, allegedly breaking their all time single issue sales record by double the previous record (when an industry is starved of credibility, it will consume a lot of it). Although the negative portrayals of multilevel marketing in the media still outnumber the positive, the latter are numerous, and the former are, for the most part, still deserved.

And MLM is still here.

Then it was "Codex Alimentarius" that was going to wipe out the vast majority of MLM companies by turning all dietary supplements that contained more that a speck of any vitamin or mineral into prescription drugs. Supposedly this was to conform with mandatory edicts created by the Food and Agriculture Organization of the United Nations and the World Health Organization.

We ranted and raved, we filled blogs and message boards with diatribes about the United States caving to the "New World Order", we wrote letters to politicians by the thousands, and we counted down the days to the dreaded 28th Session of the Codex Alimentarius Commission, to be held in Rome, Italy. That's where all these draconian, billion dollar industry destroying, not to mention life shortening new rules would be finalized, and unleashed upon us. The session was to begin on July 4th – our Independence day. Oh, the irony!

And the 28th Session of the Codex Alimentarius Commission did begin on the 4th of July, and ended on July 9th – 2005! Turns out these were all just "guidelines". They'd all really like everyone to get together and follow really low, uniform dosage standards, but we, the United States, didn't really have to. And, of course, we chose not to.

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Then came "The Big One". The earthquake that was surely going to rock the MLM industry, ultimately turning it into a pile of smoldering rubble. The FTC's New Business Opportunity Rule. One prominent constitutional attorney spoke frequently on radio shows, conference calls and before live audiences where he matter-of-factly proclaimed that the FTC was enacting this new biz opp rules solely and specifically to "destroy the network marketing industry" and it was being "fast tracked" to expedite our industry's demise by the Summer of 2007. He and another prominent industry watchdog took their "Save Our Industry!" crusade to the airwaves and across cyberspace, literally scaring up thousands of dollars in donations to fight these "jack booted thugs" that were going to "break down the doors" of independent distributors who did not conform.
In actuality, the FTC had only proposed a New Business Opportunity Rule, and had asked the public for feedback. The new rule would have applied to several other forms of business opportunities besides MLM, and would have only required greater disclosure (although some proposed methods for doing so were ridiculously overreaching and impractical). This proposed "fast tracked" new rule, which was introduced about a year earlier (April of 2006), languished for another year before the FTC, after hearing from and listening to thousands of commenters, eventually exempted all network marketing companies. And in spite of Team Little's attempt to turn all network marketers into frightened lame ducks, and their tacit declaration that our industry was terrified of disclosure...

... MLM is still here.

Then Senator John McCain (R-Arizona) was going to destroy most of the MLM industry with his "Dietary Supplement Safety Act". Supposedly, this act would have given the FDA authority to unilaterally ban any dietary supplement, or all dietary supplements. A month later, after objections from the supplement industry and discussions with others, such as Senator Orrin Hatch (R-Utah), Senator McCain withdrew his support of the act, and it died a natural, congressional death.

And MLM is still here.

More recently is was Congressman Henry Waxman (D-CA) who, according to a whole coup of Chicken Littles, was going to have the FTC do the FDA's dirty work by embedding language in "The Wall Street Reform and Consumer Protection Act of 2009" (H.R. 4173) that will give unchecked power to the FTC to ban any, or taken to its illogical extreme, all dietary supplements. According to the same two or three articles that went viral throughout the internet (creating the illusion there were thousands of opposing commentaries) Waxman added this last minute language, after the bill had already passed the House and was about to go before the Senate, to "terrorize nutritional supplement companies by greatly expanding the power of the FTC to make its own laws that target dietary supplement companies". Here's the problem with this one: It didn't. I searched the original version of this bill (all 1,279 pages) as well as the subsequent bill that went before the Senate (all 1,705 pages). There is not one word related to dietary supplements, nutritional products, DSHEA, or the word "Health" in any context (other than where Federal Employee Health Benefits is mentioned). The bill, with the Waxman language intact, became law in July of 2010. And after supposedly possessing this industry destroying power for almost 15 months now...

MLM is still here.

Which brings us to the current eminent falling of the MLM sky – the FDA's "Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications". This guidance defines how and when to notify the FDA of a "New Dietary Ingredient" (NDI) that is being introduced into the marketplace. The purpose of this notification, at least according to the FDA, is to insure the new ingredient is safe for human consumption.

Here's what Team Little is telling us about this alleged stealth attempt to reek havoc on the dietary supplement industry: According to Life Extension®, these "draconian" FDA "mandates" will "raise supplement prices, reduce allowable levels of key nutrients" and "totally remove a wide range of existing supplements from the marketplace" by "outlawing new supplements". The FDA's guidelines "are so flawed that even nutrients shown to be completely safe in hundreds of clinical human studies would fail to accommodate the new, unreasonable safety margins". Wellness Resources, Inc. makes the assertion that these guidelines will "....make all companies spend tens of thousands, even millions, to comply with drug-like approval of ingredients that have been on the market for the past 17 years with a proven track record of safety." According to Jonathan Emord, the same constitutional attorney who claimed the FTC had "fast tracked" a plan to destroy the MLM industry, the FDA's latest approach is already "causing the supplement company carcasses to form heaps along the regulatory road." Even one of our own trade associations (not the DSA or ANMP) has published dire warnings that popular MLM products based on Resveratrol and GABA will be pulled off the market. Another well respected MLM watchdog claims companies like XanGo will be forced to take their juice products off the market for several months while the FDA reviews its NDI application, and assesses its safety.
After reading dozens of end-of-supplement-days articles and blogs, many of which referenced each other as their source, I decided to see for myself what the FDA was really up to. In an effort to validate all of the hellish implications of this FDA Draft Guidance I did something that apparently few others have bothered to do – I read the FDA Draft Guidance.

It begins with the ominous line: "This guidance is being distributed for comment purposes only" (all the emphasis in these quotes are mine). In other words, the FDA is seeking our feedback (shudder) exactly like the FTC did when they published their Proposed New Business Opportunity Rule. You remember. That feedback that they listened to, and acted upon? The introductory section continues: "Contains Nonbinding Recommendations. Draft-Not for Implementation."

Not only does this draft guidance "mandate" absolutely nothing at this point, it will "when finalized… represent the Food and Drug Administration's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations."

"This guidance [does] not establish legally enforceable responsibilities. Instead, this guidance describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word 'should' in Agency guidance means that something is suggested or recommended, but not required." What a draconian attitude!

"This guidance is intended to assist industry in deciding when a premarket safety notification for a dietary supplement containing a new dietary ingredient (NDI) is necessary and in preparing premarket safety notifications." That's right. The FDA is using the honor system and allowing the manufacturer or marketer themselves to decide what is an NDI and what is not – exactly as it has been since October of 1994!

As is explained within the FDA's Draft Guidance, on October 25, 1994, the Dietary Supplement Health and Education Act, or DSHEA (pronounced d'shay), was signed into law. DSHEA amended the Federal Food, Drug, and Cosmetic Act by adding, among other provisions, sections which define the term "dietary supplement" and "new dietary ingredient". DSHEA requires the manufacturer or distributor of an NDI to submit a "premarket notification" to the FDA if the NDI was not present in a dietary supplement before October 15th, 1994. Any supplement ingredient that existed before 10/15/94 is exempt from those requiring NDI notifications. An ingredient is also exempt if it "has been present in the food supply [previous to 10/15/94]… in a form in which the food has not been chemically altered". So, again, this requirement to notify the FDA of a New Dietary Ingredient, and to make a case for its safety, is not new. It is already part of DSHEA, and has been the entire 17 years since it passed. Furthermore, dietary supplement ingredients have formally existed for more than 125 years, so all those that were introduced in the first 108 of those years are exempt. Also, all ingredients since 1994 that are already on the FDA's GRAS list (Generally Regarded as Safe) are exempt. All 293 of them, including glutathione, stevia, selenium, and lycopene.

Within the Draft Guidance the FDA explains, "DSHEA does not specify the type or amount of evidence that must be included in a NDI notification. The purpose of this guidance is to give manufacturers and distributors of these products information and recommendations to help them decide when a NDI notification is necessary and to improve the quality and quantity of NDI notifications." The dietary supplement industry has long claimed DSHEA was too vague in its definitions of "dietary supplement" and "new dietary ingredient". This is, in fact, exactly what the dietary supplement industry has been asking for for years. "After having gained some experience," the FDA says, "with the NDI notifications that have been submitted to the agency and from the many questions that industry has asked since the agency's regulation implementing the NDI notification requirement was issued, FDA has concluded that this guidance is needed to assist industry in achieving this goal (of bringing safe NDI to market). The Guidance goes on, "There are an estimated 55,600 dietary supplement products on the market, and FDA has received approximately 700 NDI notifications since we began reviewing NDI notifications approximately 16 years ago. Additionally, the Institute of Medicine has estimated that 1,000 new dietary supplements are introduced to the market each year." It seems what the FDA is essentially saying here is, if you're upset you might have to take your existing product containing an NDI off the market, you should have submitted your "premarket notification" previous to marketing it. I'm not sure that's unreasonable.
The FDA specifically states their "goal in promulgating the NDI regulation" was to ensure that NDI notifications contained the information that would enable FDA to evaluate whether a dietary supplement containing an NDI is "reasonably expected to be safe." It's interesting how we, as a society, rant and rave about how the FDA approves drugs like Vioxx, Bextra and Fen-Phen, with those in the fields of health and nutrition protesting the loudest, in spite of the FDA requiring pharmaceutical companies to spend tens-of-millions of dollars over several years conducting numerous studies and clinical trials, first in the lab, then on animals, and then on thousands of humans, to not only prove their drugs works, but that they're safe. But dare the FDA ask dietary supplement producers to show any evidence that their products are safe, and it's "unreasonable", "unconstitutional", "illegal", and "draconian". I know it's popular to bash the FDA now days, along with the FTC, the SEC, the IRS, the DMV, and just about any other government agency. But let's all step back, take a deep breath, and try to practice a little common sense here. It's a good thing that someone is trying to make sure our dietary supplements are safe. If some substance is, in fact, a "new" thing that wasn't in our supplements or food supply before, I think I would like to know if its safe to consume. I think just throwing it out into the marketplace then waiting to see how many people get sick or die is not the very best strategy. And I don't really care it it's "natural". There are all kinds of herbs, roots, seeds, fungi, cacti, and minerals that are harmful, or even deadly. Of course, if it's something like a tropical fruit that has been safely consumed by millions of people for thousands of years, well, that would just be stupid if the FDA required it be taken off the market pending an NDI notification approval. That's why, in spite of what we've been told, they don't!

In the Draft Guidance the FDA states they, "expect that when history of use evidence alone is adequate to support the safety of the NDI in the supplement, notifiers will prefer to use that route." Yes, all juice companies will still get to use "history of use evidence", as has always been the case. Counter to all the clucking we're hearing to the contrary, supplement companies will not be forced to apply the same level of testing on common, natural substances that new medications developed by drug companies are subjected to. In fact, the FDA specifically addresses this point here: "Compared to the cost and time needed to conduct clinical or animal toxicology studies, it is generally less expensive and faster to gather historical information and to conduct chemistry studies to establish the identity of the historically used materials. Submitting clinical and/or animal studies in addition to history of use data would be appropriate when the history of use evidence contains gaps or when the proposed conditions of use for the NDI differ from the historical conditions of use." In other words, the FDA is specifically guiding companies to use "history of use" evidence instead of conducting clinical trials and lab studies, and that this type of evidence would only be appropriate when the company didn't have sufficient history of use data.

The FDA could not have spelled all of this out more clearly when, within the Draft Guidance, they include the graphical "decision chart" on the next page. I've plotted out the path (see blue lines) that any supplement producer or marketer would take through this chart even if their product wasn't sold as a dietary supplement before 10/15/94, but has been in the food supply before then and has not been "chemically altered" in it's currently marketed form. Like, for example, every single exotic fruit beverage currently being sold! Noni, Aloe, Pomegranates, Mangosteen, Açaí, Goji, Amalaki, Maqui, Nopal Cactus... every single one would be, based on this chart, exempt from NDI notification.

If, however, a common, natural substance that has been consumed by millions of people for thousands of years, previous to 1994, is "chemically altered", then all bets are off. And as it should be. Remember, we're dealing with individual ingredients here, not entire supplement formulations. So when the FDA refers to chemical alteration they are referring to changing the molecular make up of a single ingredient, not the formulation of a supplement product. For example, let's take H₂O, one of the simplest, most basic, and safest chemicals on Earth. Two hydrogen molecules and one oxygen molecule. Some call it "dihydrogen monoxide". Most call it water. Chemically alter it in the most slightest possible way, by adding or subtracting a single molecule, and you have a completely different chemical. For example, add one oxygen molecule to water and you have H₂O₂. Some call this "dihydrogen dioxidio". Most call it hydrogen peroxide. Change the two hydrogen molecules to nitrogen and you have "Nitrous oxide". Better known as laughing gas. [This is literally the only thing I remember from my 10th grade chemistry class – who'da thought it'd actually use this someday?] The point being, I don't think the FDA is out of line by adding this "has not been chemically altered" stipulation.
Was the dietary ingredient marketed in the U.S. before October 15, 1994? (See IV.A.5 and IV.A.8.)

Yes → New Dietary Ingredient (NDI).

No → Have there been any proposed or implemented changes to the manufacturing process for the dietary ingredient?

Yes → Does the new manufacturing process change the identity of the ingredient (e.g., different chemical structure or composition, use of extraction, use of a different starting material, such as a different part of a botanical)? (See IV.A.11.)

No → Has the NDI been present in the food supply as an article used for food? (See section IV.B.)

Yes → Has the notifier submitted a notification to FDA for a product containing the same NDI with the same or lower NDI intake level, same composition, and same or narrower conditions of use? (See IV.C.1.)

No → Will the manufacturing process for the new product change the identity of the NDI (e.g., different chemical structure or composition, use of extraction, use of a different starting material, such as a different part of a botanical)? (See IV.B.4.)

Yes → NDI adulteration standard (21 USC 342(f)(1)(B)) applies. NDI notification required.

No → NDI adulteration standard (21 USC 342(f)(1)(B)) does not apply. NDI notification not required.

No → Not Sure → The manufacturing change may have created an NDI. NDI notification may be required. Consult with FDA.

Has the NDI been chemically altered from its conventional food form?*

* Examples of processes that do not chemically alter an ingredient are minor loss of volatile components, dehydriation, lyophilization, milling, or formation of tincture, aqueous solution, slurry, powder, or solid in suspension. See IV.B.3.

Examples of changes that chemically alter an ingredient (see IV.B.4 for more details and additional examples):

- New process makes or breaks chemical bonds.
- New solvents (except tincture or water) or post-extraction processing that changes chemical composition of mixture.
- New manufacturing method (e.g., new agricultural or fermentation conditions) that significantly changes chemical composition.
- Application of nanotechnology, if it results in new or altered chemical properties.
- New starting materials (e.g., different part of a plant) that change the chemical composition of the ingredient.

The NDI may have been chemically altered. If so, NDI notification will be required. Consult with FDA.

Is NDI intake level under the intended conditions of use, the same as, or lower than the intake from conventional food use of the NDI? (See IV.B.2.)

No → Yes to Any → The NDI has probably been chemically altered. If so, NDI notification required.

No to All → Not Sure → Pre-DSHEA Dietary Ingredient. No NDI notification required. Adulteration standard in 21 USC 342(f)(1)(B) does not apply.
As long as the juice of the fruit has not been chemically altered, and all other ingredients of the product are not NDI, then no MLM Juice company should have anything to worry about. Even if something else in the product should require an NDI notification, such as a preservative, sweetener or flavoring, then worst case the company can keep the product on the market with a substitute preservative, sweetener or flavoring until the NDI process is completed.

Dietary supplement defenders are claiming this new Draft Guidance is really a Trojan Horse that consumers will let pass through the gates based on the illusion that it's all about product safety, when in reality there are a bunch of big pharma controlled FDA bureaucrats hiding inside, waiting to emerge and attack as many sleeping supplement companies as they can. In deed, they exclaim, this new guidance will give the FDA the power to ban virtually all dietary supplements introduced since October 1994 by simply not approving their NDI submission, or allowing it to languish in the FDA's mountainous in-box for years. If supplement sellers continue to not submit NDI notifications the FDA will amass teams of new hires to audit companies and force them to submit NDI notices. Here's the problem with that – the FDA can already do this. Right now! And they've had the power to do this since DSHEA passed 17 years ago. If that was their agenda, they don't need this new draft guidance to carry it out.

The veracity of the sinister FDA/Big Pharma partnership to destroy the supplement industry ultimately falls apart when we go beyond subjectivity and speculation and simply look at historical facts. According to a study performed by the American Herbal Products Association (AHPA)\(^8\), which would be inclined to favor the dietary supplement industry, between September of 1995 and March of 2004 there were 145 unique NDI notices submitted. Seventy-seven were approved, and the FDA objected to 68 of them (19 of which resubmitted their NDI and 10 passed). Besides the fact the FDA allowed more than half (53% after the first attempt, 60% in total) to go to market, when we analyze why the other 47% were initially rejected there is not the slightest sign impropriety. Here's the breakdown:

A) 27 were rejected because the ingredient was not even a "dietary supplement". Either it was being marketed as a treatment for disease, or was not "ingested", as by definition all supplements must be (thus classifying all 27 as drugs).
B) 33 were rejected because the notices were incomplete.
C) 45 were rejected because there was not an adequate basis to "reasonably expect" that the ingredient would be safe to consume. This included 27 where A or B applied as well (many fell into more than one category which is why the total exceeds 145). So only 18 (12.4%) failed to pass FDA scrutiny not because the FDA deemed the substance unsafe, but solely due to the submitter's inability to show that is was safe.

Of the 145 opportunities for the FDA to railroad a dietary supplement completely and permanently off the market, they only took advantage of this power six times. Someone was attempting to bring to market, for human consumption, six new substances that had not appeared in the ingredient lists of any dietary supplement before 10/15/94, but were outright rejected due to the FDA's concerns that the ingredient was unsafe. Among them was Pokeweed, which even when consumed in "limited quantities" can cause, among several other side effects, watery diarrhea, vomiting (sometimes bloody), and convulsions. Consuming larger quantities can possibly cause seizures, coma and death.\(^9\) Also Echium plantagineum seed oil, which is considered poisonous. We know this because when horses eat it, they die.\(^10\) And Oleander extract (Nerium oleander), which is also classified as poisonous.\(^11\) And as hard as this is to believe, that draconian FDA, surely at the urging of all those lobbyists from Pfizer and Merck, also rejected Gamma-butyrolactone (GBL). If this one sounds familiar it's because its been in the news a lot the last few years. It's more commonly referred to as the "date rape" drug.\(^12\)

The FDA had the same ability to prevent these 87 NDIs from competing with pharmaceutical companies as they have today. But they didn't. They only found those New Dietary Ingredients to be harmful that were actually harmful! Just as they will now continue doing.

There were also a dozen NDI notifications that related to supplement products, not supplement ingredients, and numerous other notices relating to ingredients where no NDI was necessary, clearly indicating there was great confusion among supplement producers and marketers, and the need for additional detailed guidance was genuine.
Finally, there are the issues of logistics and implementation. "Navigating the new regulatory process could take hundreds of man-hours for a given product, experts say".13 This reminds me of the report commissioned by the MLMIA (which they paid several thousand dollars for) which informed the FTC that their New Business Opportunity Rule could have compliance costs of as much as $2.25 trillion dollars over the first ten years.14 Yes, that was trillion, with a "t". Although, in the case of the FDA's new Draft Guidance, no one seems to be willing to make such absurd claims, but most are essentially claiming the compliance costs will be so burdensome that most smaller suppliers will be forced out of business, and most others will have to substantially increase product costs to the consumer. However, if you actually read the section of the guidance that leaves absolutely nothing to the imagination as to what information is required, the compilation of this data will likely involve one mid-level manager and an assistant's Tuesday afternoon – if there is plenty of evidence of the NDI's safety. Like, history of use, for example. But then, if such evidence is lacking, or if the history of use involves a substance that has since been "chemically altered", then yes, proving safety will likely be burdensome – as it should be! The FDA must presumably emerge from the hip pockets of Merck and Pfizer to review their years of clinical studies on thousands of subject, with compliance costs of tens-of-million-of-dollars per substance, to show evidence of safety (a process which still fails occasionally). God forbid a dietary supplement developer must spend a few weeks, and perhaps a few thousand dollars, to show their substance is safe for consumers to consume.

On the FDA side, there are unconfirmed reports that a mere ten staff members are currently assigned to the task of reviewing NDI notifications. There is no secret the FDA is underfunded and understaffed. The last thing they need to inflict upon themselves is a tsunami of NDI notices.

One final point. Let's suspend all logic and reason for a moment and assume the FDA, like the FTC before them, really does have an ulterior motive to destroy a growing health & nutrition industry segment that provided $28.1 billion in taxable sales in 201015 16 generated from over 150 million consumers17, and directly employs over 200,000 American tax payers18, in this economy, during an election cycle. If all this were true, and thus what we all have to say about it really makes no difference and this "public comment" period is all just a charade, then why has the FDA just extended the public comment period an additional 60 days? The FTC did the same thing with their proposed new biz opp rule, and those comments significantly effected how the rule was ultimately implemented – in our favor. As of this writing only 78 comments have been submitted to the FDA (there were over 1,700 submitted concerning the FTC's new rule), but if you still care to add one more you now have until December 2nd.19

What will happen after that? I asked one prominent, very vocal opponent of this guidance that very question. He responded it was "yet to be seen". Of course it's yet to be seen! Everything in the future is yet to be seen. That's a hedge, not an answer. Here's an answer: This Draft Guidance will be revised significantly before it is cast in SiO₂+ Al₂O₃+ K₂O+ Na₂O (stone), and in favor of supplement producers and marketers. It will still just be guidance, most ingredients will be exempt, most that aren't will be deemed safe, and most companies still won't submit NDI notifications even when they are warranted. In other words, very little is going to change, other than our dietary supplements might be a little safer.

Here's the bottom line: If you're a network marketer, this won't effect yours.

Len Clements
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Since 1989, Len Clements has concentrated his full-time efforts on researching and analyzing all aspects of Network Marketing. He is a court certified expert in the field of network marketing as well as a professional consultant, speaker and trainer. He currently conducts "Inside Network Marketing" seminars throughout the world and is the author of the controversial book "Inside Network Marketing" (Prima) and the best selling audios "Case Closed! The Whole Truth About Network Marketing" and "The Coming Network Marketing Boom." To receive additional information about MarketWave and its services, please call 1-800-688-4766, or visit www.MarketWaveInc.com.
2. Nu Skin has since reformed and is now a good corporate citizen.
5. You can read my commentary on this issue here: http://www.marketwaveinc.com/viewalert.asp?id=66
16. According to the Nutrition Business Journal, the entire health & nutrition industry grew 6.6% to $117 billion in 2010.
17. http://jama.ama-assn.org/content/306/4/428.short
19. http://www.regulations.gov/#/docketDetail;dct=PS;rpp=10;po=0;D=FDA-2011-D-0376