

# NEWS RELEASE

## FDA to Reconsider Draft NDI Guidance

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Category: News Releases  
Published: 22 June 2012

The decision of the FDA has not been officially announced, but Senate staff confirms that Senators Tom Harkin, and Orrin Hatch were informed in a personal meeting on June 19<sup>th</sup> with FDA Commissioner Margaret Hamburg and Deputy Commissioner Mike Taylor that a revision may be attempted in the future. The NPA and several others immediately sent out news releases claiming it as their victory while also applauding this FDA reconsideration; but the National Health Federation and other health-freedom organizations are not applauding for several reasons:

- Let's Not Applaud the FDA for Doing What They Should Have Done Years Ago. We all knew the FDA had this card to play. Amazingly, one industry association is proclaiming that "This action by the FDA shows that they are committed to an open dialogue" and that the FDA will be releasing a revised draft guidance that "the agency hopes will provide greater clarity and address concerns that the document is not in line with the intent of the DSHEA statute." Really! So where has the FDA dialogue been for the past 17 years on issuing a Guidance? Why weren't supplement stakeholders, industry, and consumers consulted in the first place before the July 2011 Guidance was issued?
- This is No Time to Beg for Crumbs. With the backlash the FDA received from consumers, manufacturers, health-stores, and supplement manufacturers after its incredibly off-the-wall July 2011 draft Guidance came out, this option of revision (no matter how small the revisions), was anticipated by the NHF. This was exactly why the Federation came out with H.R.3380 legislation in August 2011, so that we would not have to beg for "crumbs" from the FDA during its (if any) revisions. H.R.3380, the Dietary Supplement Protection Act (DSPA) introduced by Rep. Dan Burton (R-IN), moves the defining date of October 15, 1994 (separating "old" supplements from "new" ones), to a more realistic and recent date of January 1, 2007. By this one simple act, the Bill encompasses within that previous grandfathering clause all of the "new" dietary-supplement ingredients that have appeared in that 13-year interval and that would otherwise be subject to the onerous requirements of the FDA Guidance. The bill drastically narrows the arbitrary power the FDA wants to exercise over new supplements and thereby protects thousands of supplements that have been safely consumed from being removed from the marketplace.
- The Industry Historically Loses at the Negotiating Table. Typically, the FDA wins over health freedom whenever there are simply negotiations between it and the industry or between it and consumers. Do we really expect it to be any different

this time? How many times do we have to be slapped in the face before we realize that we will be slapped yet again? Make no mistake about it: The FDA's goal is to usurp our health rights as they have continuously done for decades. The FDA at revision time is still ignoring the true intent of the Dietary Supplement Health and Education Act (DSHEA). Any revisions to the draft Guidance will just be cosmetic changes. More lipstick! Every time we let the FDA do this to us, we set a precedent and their strength gets stronger and ours weaker. In the Federation's comments submitted to the FDA in December 2011 ([found here](#)) about the July draft Guidance, we urged the FDA to withdraw the Guidance. We knew the odds of this actually happening were slim as the Guidance is nothing more than the FDA's further efforts to help its pharmaceutical-industry friends by squelching supplements and the competitive threat they pose to drugs.

- The Regal FDA Has Thrown Us a Crumb and Industry Cheers. This latest development sets the stage for the continuation of regulatory misinterpretation, confusion, and misguided enforcement by the FDA. H.R.3380 is a longer-term solution to effectively addressing these issues – not a band-aid or begging with hat-in-hand approach. It also keeps the pressure right where it belongs – on the FDA.
- It's Way Too Early to Announce Victory. What is now being touted as a “monumental breakthrough” in FDA cooperation is in reality just the old Washington cliché of “you are either at the table or on the menu” with an out-of-control FDA bureaucratic and Federal government anti-individual liberty philosophy at play. More importantly, being “at the table” ensures that you can also have your seat at the table pulled out from under you and wind up as the entrée anyway. For example, the FDA announcement singled out the issue of establishing an agreed-upon list of “grandfathered ingredients” as an area where the FDA would like to “begin working with industry” to resolve. Industry has already admitted that the records of ingredients on the market before 1994 no longer exist. Supplements and their ingredients on the market before October 15, 1994 were “grandfathered in” by DSHEA and therefore exempted from having to prove in any way that they are safe. So what happens when agreement is not reached with the FDA in these upcoming talks? Obviously, the FDA position is that these new dietary ingredients will have to be removed from sale to Americans until they have been “proven” safe to consume. We lose, not the FDA.
- We Still Need to Keep The Pressure On FDA. Recently, the FDA decision to send out warning letters to ten companies with “new” dietary ingredients, *even though the draft Guidance had not even yet been finalized*, is just another example of why our *Dietary Supplement Protection Act* (H.R.3380) is needed and needed now. Just hoping that negotiations with the FDA will produce tangible results is foolish. Even attorney Jonathan Emord has acknowledged that “substantial changes are rare” on the part of the FDA. Pressure must be kept on the FDA.

The Federation asks that true supporters of health freedom not settle for FDA crumbs during the revision time (and who knows how many years that will be?), but

support H.R.3380 and request that your Representative co-sponsor our Bill. This does not mean that Industry should not talk with the FDA, only that it should do so from a position of strength and not weakness.

We sincerely hope that talks with the FDA will produce results, but does anyone really think that they can trust the good intentions of the FDA? As NHF President Scott Tips says, *“To pin all of our hopes on the good graces and good will of the FDA is the height of folly. If they had such good will, then where were they for the last 17 years? In fact, where were they in ‘listening to the Industry and consumers’ prior to drafting their Guidance on NDIs? Nowhere. They were MIA. And so, now, just because they have thrown us a scrap, we are to believe that they have suddenly seen the light? Are we really that gullible?”*

The Federation wants more than revisions to this draft Guidance and we don't want to settle. Remember, as we've always said, “politicians don't see the light, they only feel the heat.” It's time to renew the pressure on the FDA by passing the Dietary Supplement Protection Act (H.R.3380). Contrary to rumors, **H.R.3380 can pass**. Keep up the pressure!

**Join the NHF in demanding our dietary-supplement rights via H.R.3380**

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