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FDA announces current Good Manufacturing Practices (cGMP) for Dietary Supplements

On June 25, 2007, the FDA released its long-awaited final rule on GMPs for the Dietary Supplement Industry. Critics wonder what took the FDA so long to issue these GMPs since the Dietary Supplement Health and Education Act (DSHEA) of 1994 stipulated that the FDA would provide the industry guidance for quality standards in manufacturing.

Nature's Sunshine Products has always had GMPs in place since the inception of our manufacturing plant. Anyone who has toured our facility in Spanish Fork, Utah has seen the signs designating GMP areas. This means that quality standards such as hairnets, beard nets and uniforms or smocks must be worn in those areas. This prevents the contamination of food grade supplements during the production process. But that is just one small example.

The real bulk of the work in GMP manufacturing is record keeping. Tracking who did the work, who checked the work that was performed, and noting what date the work was completed assigns responsibility to the process and proves that the work was done. In a nutshell, GMPs assure that quality standards are enforced and upheld.

So what is all the excitement about the FDA's final rule on GMPs? The FDA is not stepping in and wielding its power over the supplement industry. These new GMPs may put low-quality manufacturers out of business and will create hurdles for manufacturers who do not have a current GMP program in place. But at NSP, it is business as usual. We've closely analyzed the final rule, and NSP is already in compliance with the FDA's newly proposed final rule of GMPs. Let's take a quick look at what the final rule requires of manufacturers.

Dietary Supplement manufacturers must perform activities in manufacturing, packaging, and labeling of dietary supplements to ensure that products contain ingredients which are claimed on the label and are not contaminated with pesticides, heavy metals or other impurities.

100% identity testing—Manufacturers must use at least one appropriate test to determine the identity, purity and strength of any component of a dietary supplement.

This means that supplement manufacturers at some point must conduct at least one test to assure that their product contains the ingredient listed on the label. Nature's Sunshine Products already exceeds this. We test <u>all</u> incoming raw materials for proper identification, purity and contaminants. We do in-process testing to ensure that the ingredients were mixed and encapsulated correctly. We test to ensure that active ingredients have been preserved in the process. Finally, we conduct finished product testing to verify that we are meeting ingredient label claims. We consider this a high-quality GMP program.

The following examples demonstrate routine quality testing that extends beyond the scope of the cGMPs.

- We have analyzed Black Walnut that was produced during a wet season. It appeared to be quality material, but it didn't contain the active constituents.
- We've also seen the incorrect species come into our warehouse. An example of this type of quality testing involves Valerian root. *Valeriana wallichii* (Indian Valerian) was identified by trained technicians using High Performance Liquid Chromatography. This species is inferior and an incorrect substitution for *Valerian officinalis,* the ingredient which appears on our label.

Another example of quality testing employs Thin Layer Chromatography (TLC) conducted on powdered material. By comparing band separations on TLC plates, we can verify that the correct plant part is being used. Once an herb is ground into powder, it is very difficult to determine the plant part used unless you do this type of qualitative analysis. These are just a few examples of how NSP's Quality Assurance department is compliant with the cGMPs.

We applaud the FDA for announcing the final rule GMPs, but we know from experience that our superior products are the result of quality and integrity in manufacturing. We know that when people use the correct plant species, plant part and properly harvested material, they experience the results they seek. We have seen this for years in the industry. Raw materials that are rejected by NSP are not discarded, but are sent back to the suppliers who may in turn sell that same material to our competitors. The announced cGMP final rule demonstrates FDA sensitivity to promote quality in manufacturing. A high-quality GMP program is always changing and evolving with new technology, new ingredients, new regulations and new industry challenges. At NSP, we cannot rest on our laurels by maintaining cGMP compliance. We actively seek new and better ways to build quality manufacturing practices into our facility in order to produce the highest quality products possible.