Explaining Pharmaceutical Grade

Are the USANA Nutritionals pharmaceutical grade?

Answer:
If you look at the bottom of the Essentials and other product labels, you will find the following statement, "Laboratory tested, quality guaranteed. Meets USP specifications for potency, uniformity, and disintegration where applicable." This standard holds true on all applicable products we manufacture.

Pharmaceutical grade tablets and capsules must meet certain standards for quality as set by the United States Pharmacopoeia or USP. The USP is a non-profit organization that works closely with the Food and Drug Administration (FDA), the pharmaceutical industry, and health professionals to establish authoritative standards. These standards are enforceable by the FDA and the governments of more than 35 other countries, and are recognized worldwide as the hallmark of quality. USANA chooses to manufacture its products according to these rigid quality standards.

The primary factor that separates USANA from other nutritional supplement companies is the high standards of manufacturing. In 1994, the Dietary Supplement Health and Education Act (DSHEA) was enacted by the United States Congress. Within this act, Nutritional Supplements were reclassified from "food" status to a new category called "Dietary Supplements" (DS). Because of DSHEA, certain changes were made to regulate dietary supplements differently than food. The first noticeable change effected the way DS were labeled. The "Nutritional Facts" panel seen on foods was changed to a "Supplement Facts" panel on DS. You may notice DS labels do not declare calories, fat, carbohydrates, or proteins. Dietary supplements, however, declare nutrient values for vitamins, minerals, herbs, etc.

The second change allowed dietary supplement makers to include health claims (normally associated with drugs) that were not permitted for foods. For example, the FDA approved only 4 health claims for foods; high fiber and a reduction to cancer, calcium and osteoporosis, etc. Under DSHEA, DS products could extend health claims in the area of structure/function (i.e. vitamin E nutritionally supports good cardiovascular function).

The last change effected by DSHEA concentrated on DS quality. Directed by DSHEA, the FDA was to establish GMP (Good Manufacturing Practice) guidelines for the dietary supplement industry and model the rules using current Food GMP regulations. GMP is the minimum quality expectation for a given product used by the consumer. Since 1994, FDA has not established and enforced GMP regulations for DS. Therefore, DS products are currently monitored under food GMPs.

When looking at the two current regulations (Food GMP vs. Drug GMP), there are several dramatic distinctions. We will use a pizza vs. penicillin analogy to help illustrate this point. If you want to research the differences yourself, or just verify the next statements, you can find these rules in the Code of Federal Regulations - 21 CFR 110 (Food), 21 CFR 210 and 211 (Drug).

Food GMPs focus more on the product as a "safe" food item. Basically it ensures that no harmful

poisons or pathogenic biological elements are introduced into the finished product. Food GMPs do not mandate you test each batch or its ingredients for these harmful elements. The only actual stipulations for a manufacturer are: 1.) they use ingredients generally recognized as safe for human use and 2.) they maintain good hygienic practices. For example, when you order a pizza the maker uses flour, yeast, salt, water, tomato paste, and cheese. It is not necessary to test these ingredients individually for safety because they are all generally recognized as safe. Provided the chef runs a clean shop, they are fully compliant with food GMPs.

Since DS are regulated under food GMPs, it has created numerous problems for the industry. Remember, food GMPs do not mandate that finished DS products, or ingredients used in DS products, be tested to verify label claims. Consequently, if you manufacture a 100 mg Vitamin C product, under the current law you are not required to test the Vitamin C raw material, or the finished product to verify that it actually contains 100 mg of Vitamin C. Many manufactures do not go to the added expense because it is not required. As a result, cheap, low-grade, non-potent DS products have flooded the market place. Many independent studies and recent news articles have illustrated this quality problem by highlighting less than stellar results from tests of commonly retailed products. Indeed, the newly proposed GMP rules for DSHEA may not stop these practices. Unfortunately, the few manufacturers that have strict standards, such as USANA, are unfairly compared to those who only follow food GMPs.

Do you expect a different level of quality for penicillin than you do for pizza? Of course you do. Because of this difference in expectation, Drug GMPs are more restrictive. Remember, food GMPs are only focused on safety. By contrast, drug GMPs are focused on safety, potency, purity, and efficacy. Drug GMPs mandate ingredient (raw material) testing to show safety, potency, purity and efficacy. It also mandates safety, potency, purity and efficacy testing on each batch of finished product. Hygienic practice is also more restrictive. Other items such as uniformity, validation, process controls, and stability are required. These are terms never discussed under food GMPs and are only applicable under drug GMPs.

The foundation of USANA's product quality is pharmaceutical GMPs. We do not endorse the philosophy of other DS manufacturers who only follow food GMPs. It would be irresponsible for USANA to do extensive research to develop high-quality products, and then give distributors pizza quality.

Many distributors ask us whether the FDA has audited our facility for drug GMP compliance. They want to verify we follow drug GMP regulations. The answer is no. Because the FDA considers our products as DS, the audit would be to food GMPs only. However, our products are considered over-the-counter drugs in Canada and Australia and we have been audited to drug GMPs by the FDA equivalents in those countries.