U.S regulations just got tougher for dietary supplement ingredient suppliers

. . . understanding the new food safety modernization act (FSMA)

In January 2013, the U.S. Food and Drug Administration (FDA) published several new rules to support and strengthen the United States' food safety system. These rules have important implications for suppliers of dietary supplement ingredients.

While the new rules will affect ingredients suppliers, they will not impact manufacturers of finished products. The finished products – items like tablets, capsules, powders, liquids and soft gels – are already regulated under a separate regulation: 21 CFR 111 Good Manufacturing Practices (GMPs). Dietary supplement ingredient suppliers were exempted when 21 CFR 111 was enacted. These new rules are aimed at bringing suppliers of ingredients like vitamins, minerals, fish oil and glucosamine up to the same regulatory standards and requirements as manufacturers of finished products.

If you are an ingredient supplier to a dietary supplement manufacturer in the United States, you'll need to prepare for the new regulatory requirements in order to avoid costly delays as you export ingredients. No one wants to ship a large container of fish oil all the way from China to the United States only to have it held up in customs due to inadequate procedures and registrations.

While the final regulations have not been released, the FDA has provided guidance to help ingredient suppliers prepare for the new requirements. Now is the time to learn about these new requirements and start preparing for them.

The rules affecting dietary supplement ingredient suppliers fall into three categories:

- Prevention Controls for Human Food
- Foreign Supplier Verification for Importers
- Accredited Third Party Certification

The first rules, Prevention Controls for Human Food, have already been published. We expect the rules related to Foreign Supplier Verification for Importers and Accredited Third Party Certification to be published soon. Let's take a closer look at each of these categories of rules.

Prevention Controls for Human Food

Under the new Preventive Control rules, dietary supplement ingredient suppliers will be required to have a written plan that:

- Evaluates hazards that are reasonably likely to occur in their ingredients, such as pathogens and allergens,
- Specifies the steps that will be put in place to minimize or prevent those hazards,
- Specifies how these controls will be maintained,
- Maintains routine records of the monitoring, and
- Specifies what actions will be taken to correct problems that may arise.

With GMP and Hazard Analysis for Critical Control Points (HACCP) systems already in place throughout Europe, we expect most European ingredient suppliers will be well prepared to meet the new Preventive Controls for Human Food rules. But ingredient suppliers in other parts of the world may have significantly more work to do to meet these new requirements.

Foreign Supplier Verification for Importers

While these rules have not yet been published, we expect they will require U.S. importers to verify that foreign ingredient suppliers are following procedures that provide the same level of health protection that is required of U.S. ingredient producers.

Accredited Third Party Certification

This rule is expected to put a process in place to accredit third party auditors to ensure ingredient suppliers in other countries comply with U.S. food safety laws. Accredited third party auditors will undoubtedly use cGMP and HACCP guidelines as part of their inspection processes. NSF expects to be one of the first third party auditors accredited to perform inspections on behalf of the FDA.

Clearly, many of the details are still up in the air. So how do you prepare for these new regulations? Even though many of the specifics are unclear, dietary supplement ingredient suppliers should begin by asking themselves a few questions to evaluate their readiness for the new regulations. These questions include:

- What type of food safety systems do you currently have in place? Are you adhering to the cGMPs?
- Do you have a HACCP program in place?
- Do you have a system in place to trace your raw materials once they leave your warehouse?
- What type of testing are you currently performing to verify your ingredients meet their specifications? Are you performing microbial testing for ingredient safety?

As we await final publication of the rules, these basic questions will help you prepare for these new, tougher U.S. regulations. A qualified consulting firm specializing in dietary supplements like NSF International can also help you determine your readiness for the new regulations and avoid potentially costly delays. NSF International is The Public Health and Safety Company™, providing public health and safety risk management solutions to companies, governments and consumers around the world. For more information about NSF International's Dietary Supplements program, please visit www.nsf.org

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