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Legal Review: New FDA Dietary Supplement Rule Presents Challenges

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Response

Marketers are coming under increasing scrutiny because of government-ordered recalls of products that have the potential to harm users. A new final rule recently issued by the United States Food and Drug Administration (FDA) increases the risk of a product recall to marketers of dietary supplement products on grounds of misbranding.

The rule establishes current Good Manufacturing Practices (cGMPs) relating to manufacturing, packaging, labeling and holding of dietary supplements to ensure their quality and safety. Companies that fail to comply with cGMPs run the risk that the manufactured product would be considered misbranded and subject to a recall, as well as the attendant negative publicity such an action would generate.

The Background

Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), dietary supplement manufacturers are responsible for substantiating the safety of the dietary ingredients used in manufacturing a product, and for assuring that product claims are not false or misleading. While the FDA has previously taken enforcement action against dietary supplement products that have been adulterated or otherwise misbranded, the recently issued final rule establishes formal cGMPs requirements - akin to that required of drug manufacturers - for the manufacturing, packaging, labeling, and holding of dietary supplements.

The rule is intended to establish standards in the manufacturing processes of dietary supplement products and to prevent the inclusion of incorrect ingredients, too much or too little of a particular dietary supplement ingredient, contamination by substances such as natural toxins, bacteria, pesticides, glass, lead and other heavy metals, as well as controlling packaging and labeling.

Who Is Subject to the Rule?

The final rule does not expressly apply to marketers or even suppliers or producers of dietary ingredients, but instead places the burden of compliance completely on the manufacturers. However, because a dietary supplement product that fails to comply with the rule risks a "misbranded" finding, marketers must take steps to ensure that their manufacturers are in compliance with the requirements. Otherwise, they risk product recall and bad publicity.

The cGMPs apply to all domestic and foreign companies that manufacture, package, label or hold dietary supplements, including those involved with the activities of testing, quality control, packaging and

labeling, and distribution of these products in the U.S. No prior company or product registration is required. Any dietary ingredient used in a dietary supplement product will be required to pass "100 percent" identity testing. Firms will be required to verify the identity of any components that are dietary ingredients, and confirm the identity of "other components."

In order for an ingredient of a supplement to be a "dietary ingredient," it must be one or any combination of the following substances: a vitamin, mineral, herb or botanical, amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent or extract.

Under the new dietary supplements cGMPs, manufacturers are required to:

- Employ qualified employees and supervisors
- Design and construct physical facilities in a manner to protect dietary ingredients and dietary supplement products from becoming adulterated during manufacturing, packaging, labeling and holding
- Use equipment and utensils that are of appropriate design, construction and workmanship for their intended use
- Establish, use and maintain master manufacturing and batch production records
- Establish procedures for quality control operations
- Hold and distribute dietary supplements and materials used to manufacture dietary supplements under appropriate conditions of temperature, humidity, light and sanitation, so that the quality of the dietary supplement is not affected
- Keep a written record of each product complaint related to cGMPs
- Retain records for one year past the shelf life date, if shelf life is used, or two years beyond the date of distribution of the last batch of dietary supplements associated with those records

The final cGMPs and the interim final rule became effective August 24, with compliance phased in during a three-year period, depending on the size of the business. Companies with more than 500 employees have until June 2008 to comply, while companies with less than 500 employees have until June 2009, and companies with fewer that 20 employees have until June 2010.

What Should Marketers Do?

Marketers that manufacturer their own products are obviously directly subject to the rule and must make sure that they have cGMP protocols in place. However, marketers must be cognizant of their manufacturers' obligations and take reasonable steps as part of an ongoing due diligence process to make sure that their manufacturers are complying with the rule.

This can include contractually obligating manufacturers to comply with the cGMP requirements and requesting and reviewing on an ongoing basis the cGMP protocols utilized by the manufacturer. Marketers should require that they be provided with any notices of FDA inspections and any noted deficiencies, and confirm that the manufacturers are complying with their regulatory obligations.

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