FDA Issues Dietary Supplements Final Rule

The U.S. Food and Drug Administration today announced a final rule establishing regulations to require current good manufacturing practice (CGMP) for dietary supplements. The rule ensures that dietary supplements are produced in a quality manner, do not contain contaminants or impurities, and are accurately labeled.

"This rule helps to ensure the quality of dietary supplements so that consumers can be confident that the products they purchase contain what is on the label," said Commissioner of Food and Drugs Andrew C. von Eschenbach, M.D. "In addition, as a result of recent amendments to the Federal Food, Drug, and Cosmetic Act, by the end of the year, industry will be required to report all serious dietary supplement related adverse events to FDA."

The regulations establish the CGMP needed to ensure quality throughout the manufacturing, packaging, labeling, and storing of dietary supplements. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and the finished product. It also includes requirements for recordkeeping and handling consumer product complaints.

"The final rule will help ensure that dietary supplements are manufactured with controls that result in a consistent product free of contamination, with accurate labeling," said Robert E. Brackett, Ph.D., director of FDA's Center for Food Safety and Applied Nutrition.

Under the final rule, manufacturers are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or do not contain the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

The aim of the final rule is to prevent inclusion of the wrong ingredients, too much or too little of a dietary ingredient, contamination by substances such as natural toxins, bacteria, pesticides, glass, lead and other heavy metals, as well as improper packaging and labeling.

The final rule includes flexible requirements that can evolve with improvements in scientific methods used for verifying identity, purity strength, and composition of dietary supplements.

As a companion document, FDA also is issuing an interim final rule that outlines a petition process for manufacturers to request an exemption to the cGMP requirement for 100 percent identity testing of specific dietary ingredients used in the processing of dietary supplements.

Under the interim final rule the manufacturer may be exempted from the dietary ingredient identity testing requirement if it can provide sufficient documentation that the

reduced frequency of testing requested would still ensure the identity of the dietary ingredient. FDA is soliciting comment from the public on the interim final rule. There will be a 90-day comment period, ending on September 24, 2007. Comments may be addressed to the Division of Dockets Management Branch at www.fda.gov/dockets/ecomments.

The final CGMP and the interim final rule are effective August 24, 2007. To limit any disruption for dietary supplements produced by small businesses, the rule has a three-year phase-in for small businesses. Companies with more than 500 employees have until June 2008 to comply, companies with less than 500 employees have until June 2009 to comply, and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

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