

Final Rule for Dietary Supplement GMPs

June 28, 2007

On June 25, the FDA issued the long-awaited good manufacturing practice (GMP) requirements for dietary supplements.¹ The final regulation applies to all firms that manufacture, package, label, or hold dietary supplements, unless specifically excluded (e.g., retail establishments). Manufacturers of dietary ingredients and other components are not subject to the final rule.

In the preamble to the final regulation, the FDA states that the intent of the GMP requirements is to ensure that dietary supplements meet their established product specifications and are not contaminated during manufacturing operations. To ensure that product specifications are met, one of the most significant requirements will be that supplement manufacturers confirm the identity of each dietary ingredient prior to use by testing or examination. Under the final rule, reliance on a certificate of analysis, or even test data, from the supplier will not be considered sufficient to confirm dietary ingredient identity. The FDA acknowledges, however, that 100% identity testing for dietary ingredients may not always be necessary, and has issued an interim final rule setting forth procedures by which a supplement manufacturer may apply for an exemption from the 100% testing requirement.² Under the interim rule, a supplement manufacturer would submit a petition (under the citizen petition process³) to the FDA for an exemption, including a scientific rationale and data to support the conclusion that an alternative testing scheme is sufficient to ensure the correct identity of dietary ingredients. The FDA is soliciting comments on the proposed petition process, and has requested that comments be submitted by September 24, 2007.

To further ensure the quality of dietary supplements, the GMP requirements also call for firms to establish controls for the following aspects of supplement manufacturing:

- Personnel
- Physical plant and grounds

¹ Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34,751 (June 25, 2007) (to be codified at 21 C.F.R. pt. 111).

² Petition to Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34,959 (June 25, 2006) (to be codified at 21 C.F.R. pt. 111).

³ 21 C.F.R. § 10.30.

- Equipment and utensils
- Production and process controls, including:
 - Production and process control system
 - Quality control system
 - Receipt of components, packaging, labels, and product to be packaged or labeled
 - Master manufacturing records and batch production records
 - Laboratory, manufacturing, and packaging/labeling operations
- Holding and distribution

Additionally, the final rule requires that manufacturers establish and maintain written procedures for the following operations:

- Personnel, including employee training and hygienic practices
- Cleaning of the physical plant, including pest control
- Calibration of instruments, and controls for calibrating, inspecting, and checking automated, mechanical, or electrical equipment.
- Maintaining, cleaning, and sanitizing equipment and utensils
- Quality control operations, including the conduct of material reviews and approval/rejection of reprocessing
- Receipt, examination, and quarantine of components, packaging, labels, and product to be packaged/labeled
- Laboratory operations
- Manufacturing operations
- Packaging and labeling operations
- Holding and distribution operations
- Returned product
- Product complaints

Supplement firms have until June 25, 2008 to bring their operations into compliance with the final GMP requirements, although an extension is provided for small businesses. Firms with fewer than 500 full-time employees, but more than 20, have until June 25, 2009 to comply, and firms with fewer than 20 full-time employees have until June 25, 2010.

If you have any questions concerning the dietary supplement GMP requirements, please contact either of the following Morgan Lewis attorneys:

Washington, D.C.

Beth Bierman	202.739.5206	mebierman@morganlewis.com
Michele Buenafe	202.739.6326	mbuenafe@morganlewis.com

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