ALERTS AND UPDATES

FDA Issues Guidance on Dietary Supplement cGMP Regulations

January 27, 2011

In its recent guidance on the Dietary Supplement Current Good Manufacturing Practice Rule ("the DS cGMP"), the U.S. Food and Drug Administration (FDA) has provided a detailed road map of the requirements set forth in the regulations at 21 C.F.R. § 111.

Who must comply with the DS cGMP?

Entities or individuals who manufacture, package, label or hold a dietary supplement are subject to the DS cGMP. However, there are some exceptions, highlighted below.

- Retail establishments that sell directly to consumers are exempted from complying with the DS cGMP. However, a warehouse or other storage facility that is holding a dietary supplement for a retailer does not fall within the exception. Moreover, a dietary supplement manufacturer that sells directly to consumers must comply with the DS cGMP.

- Contractors may also be exempt from the rule if the primary control of the dietary supplement remains with the manufacturing firm. Under this rationale, a contractor who receives a dietary supplement for packaging from the manufacturer and then returns it to the manufacturer for future sale is not required to comply with the DS cGMP. The FDA views the dietary supplement as remaining within the control of the manufacturer. Broadly, the guidance appears to indicate that the FDA will determine which regulations apply to a contractor based on the contractor's role in the manufacturing process.

- Practitioners may anticipate some leniency in the FDA's enforcement of the DS cGMP. For example, the FDA does not view practitioners who provide one-on-one consultation services, which may involve the practitioner providing an end-user with a formulation, as requiring the same types of controls established by the DS cGMP. It is important to note that because this is an exercise of enforcement discretion, the FDA could alter this position. The guidance further indicates that the FDA intends to enforce the DS cGMP on practitioners who prepare batches of dietary supplements and sell them to individual consumers without one-on-one personal consultations or to practitioners who prepare batches of a dietary supplement with a known safety concern.

How does the DS cGMP relate to the food GMP rule (21 C.F.R. § 110)?

The FDA guidance indicates that the DS cGMP duplicates the requirements set forth in the food cGMP rule (21 C.F.R. § 110) to the extent that the FDA found appropriate. Where a food cGMP rule conflicts with the DS cGMP, a company manufacturing, packaging, labeling or holding a dietary supplement would likely be expected to comply with the DS cGMP.

What does the DS cGMP require?

Aside from the general provisions, the rule sets forth seven broad categories for compliance:

- Personnel (Subpart B)
- Physical Plant and Grounds (Subpart C)
- Equipment and Utensils (Subpart D)
- Production and Process Control Systems (Subparts E through L)
- Holding and Distributing (Subpart M)
- Returned Dietary Supplements (Subpart N)
- Product Complaints (Subpart O)
- Records and Recordkeeping (Subpart P)

The DS cGMP requires companies to design and implement a system of production and process controls such that each dietary supplement is packaged and labeled in compliance with a "master manufacturing record." The requirements for a master manufacturing record are set forth in Subpart H. Quality control personnel are required to review and approve the production and process control system.

The DS cGMP requires that specifications be set at any stage in the manufacturing process where necessary to ensure quality of the dietary supplement. While the DS cGMP requires specifications to be set for the components used in the manufacture of the dietary supplement, labeling and packaging, finished batches, and products received from a supplier, it does not require specifications to be established for dissolution, disintegration or bioavailability of the dietary supplement. The DS cGMP also does not insist that an expiration date or shelf date be established. However, the FDA maintains that if one of the aforementioned specifications is established, data must be available to support it. In other words, if entities or individuals choose to label their dietary supplement with an expiration date, that date must be validated before it is placed on their product's label.

For Further Information

For further specifics on the FDA's guidance and the DS cGMP or any other questions regarding this *Alert*, please contact Frederick R. Ball, any of the health law attorneys in the Pharmaceutical & Biotechnology industry group or the Duane Morris lawyer with whom you regularly are in contact.