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FDA Issues Final Rule Regarding Current Good Manufacturing Practices for Dietary Supplements

On Monday, June 25, 2007, after a ten-year rulemaking process, the U.S. Food and Drug Administration (FDA) published regulations prescribing current good manufacturing practices (CGMPs) for the manufacturing, packaging, labeling and holding of dietary supplements.¹ The new rules will have a major impact on the business operations of dietary supplement manufacturers and distributors by regulating nearly every aspect of manufacturing and distribution of dietary supplements with the potential to impact product quality. The new rules include requirements for written procedures, recordkeeping and quality control review to assure dietary supplement quality.

Previously, dietary supplement manufacturing and distribution were regulated under “umbrella” CGMPs established for food generally, a far more flexible and less prescriptive regulatory framework than the recently published final rule. Certain aspects of the new rule, such as FDA’s assertion of authority to access CGMP records, are potentially subject to legal challenge.

Although the rule becomes effective August 24, 2007, FDA has established a compliance date of June 25, 2008, to allow businesses to implement necessary changes. Businesses with fewer than 500 full-time equivalent employees and with fewer than 20 full-time equivalent employees will have until June 25, 2009, and June 25, 2010, respectively, to comply.

¹ 72 Fed. Reg. 34751-34958 (June 25, 2007). Available at: <http://www.fda.gov/OHRMS/DOCKETS/98fr/07-3039.pdf>.

Background

Although not defined by statute, FDA has informally defined CGMPs as “the methods used in, and the facilities and controls used for, product manufacturing and related activities.” FDA has utilized the umbrella CGMPs for food in their current form for the regulation of dietary supplement manufacturing and distribution since 1986. The food CGMPs were issued based on FDA’s authority to prevent adulterated food from entering the marketplace. The Dietary Supplement Health and Education Act of 1994 (DSHEA) provided FDA with specific authority to issue CGMPs for dietary supplements, specifying that they must be modeled after those for food. In 1997, FDA issued an advance notice of proposed rulemaking, seeking industry and public input to help shape the regulations. In 2003, FDA issued a proposed rule and again sought comments. Numerous substantive comments were submitted to FDA during both stages of proposed rulemaking. Although the final rule is similar to the 2003 proposed rule in many ways, a number of significant changes were made, based on comments submitted and on FDA’s own initiative.

Highlights of the New Rule

The final rule occupies over 200 pages of the Federal Register, only 17 of which are the actual regulations, with the remainder devoted to discussion and supporting materials. Dietary supplement manufacturers and distributors will require significant time and human resources to digest and implement the new CGMPs. Below are

highlights of some of the major provisions of the rule, taken from the Federal Register notice.

The final rule:

- Applies to persons who manufacture, package, label or hold dietary supplements unless subject to an exclusion;
- Establishes minimum requirements for personnel, physical plant and grounds, and equipment and utensils;
- Requires the establishment and use of written procedures for certain operations, including those related to equipment, physical plant sanitation, certain manufacturing operations, quality control, laboratory testing, packaging and labeling, and product complaints;
- Requires the establishment of specifications in the production and process control system that will ensure dietary supplements meet the identity, purity, strength and composition established in specifications and are properly packaged and labeled as specified in the master manufacturing record;
- Provides for the option to use a certificate of analysis (for specifications other than the identity of a dietary ingredient) from a component supplier instead of having manufacturers conduct tests or examinations on the components they receive;
- Requires testing of a subset of finished batches of dietary supplements based on a sound statistical sampling or, alternatively, testing all finished batches;
- Requires implementation of quality control operations to ensure the quality of a dietary supplement;
- Requires the preparation and use of a written master manufacturing record for each unique formulation of manufactured dietary supple-

ments, and for each batch size, to ensure your manufacturing process is performed consistently and to ensure uniformity in the finished batch from batch to batch;

- Requires the preparation of a batch production record every time a dietary supplement batch is made. The batch production record must accurately follow the appropriate master manufacturing record;
- Requires the establishment and use of laboratory control processes related to establishing specifications and to the selection and use of testing and examination methods;
- Requires reserve samples of dietary supplements to be held in a manner that protects against contamination and deterioration;
- Requires identification and quarantine of returned dietary supplements until quality control personnel conduct a material review and make a disposition decision;
- Requires quality control personnel to conduct a material review and make a disposition decision under certain circumstances;
- Requires a qualified person to investigate any “product complaint” that involves a possible failure of a dietary supplement to meet any CGMP requirement, with oversight by quality control personnel; and
- Requires records associated with the manufacture, packaging, labeling or holding of a dietary supplement to be kept for one year beyond the shelf life dating (when such dating is used, such as expiration dating, shelf life dating or “best if used by” dating), or if shelf life dating is not used, for two years beyond the date of distribution of the last batch.

Changes from the Proposed Rule

FDA acquiesced to a number of industry objections, as reflected in the discussion

of submitted comments. One provision in the proposed rule would have required that manufacturers maintain documentation for the generally recognized as safe (GRAS) status of any ingredient that is not (1) a “dietary ingredient” (*i.e.* not an ingredient that supplements the diet, but an additive or excipient) or (2) listed in FDA regulations as an approved additive or GRAS ingredient. Moreover, FDA maintained in the proposed rule that an FDA no-objection letter to a GRAS Notification would not have been sufficient documentation. FDA’s position would have required manufacturers to document self-GRAS positions as part of CGMP for many of the common excipients that do not have explicit clearance for use in dietary supplements. Although FDA agreed to separate this requirement from the CGMPs, the Agency reiterated that such ingredients need to be GRAS to be lawfully used in dietary supplements.

Another important change from the proposed rule is that manufacturers will be allowed to rely on suppliers’ certificates of analysis for ingredient specifications (other than the identity of a dietary ingredient), but only if they “qualify” the supplier, which involves initial and periodic auditing of the supplier. The proposed rule would not have allowed reliance on supplier certificates and would have required that a manufacturer conduct its own testing. Although manufacturers must still conduct their own identity testing for dietary ingredients under the final rule, a companion interim final rule published the same day allows manufacturers to petition FDA for an exemption from 100% identity testing if alternate means can be used to provide appropriate assurance of the identity of the dietary ingredient. The final rule also places a greater emphasis on process controls and preventive measures than did the proposed rule and reduces the requirements related to finished batch testing.

Outstanding Legal Issues

Industry voiced a number of objections to the final rule. Two of the more significant legal objections complained that:

- (1) the rules were not “modeled after” food CGMPs as required by statute; rather the rules went far beyond what is required for conventional foods and are more similar to those for drugs, even exceeding requirements for drug CGMPs in some respects; and
- (2) FDA does not have statutory authority to require that it be allowed access to CGMP records during inspections.

FDA defended its position on both of these legal objections in the final rule. While acknowledging that the dietary supplement CGMPs are more detailed

and prescriptive than the umbrella food CGMPs, it noted that — like the final dietary supplement CGMPs — CGMP regulations for certain specific food types (infant formula, canned foods and bottled water) are also more detailed and prescriptive than the umbrella food CGMPs, but are nonetheless “food” CGMPs. Also, FDA argued, to the extent that the dietary supplement CGMPs resemble drug CGMPs, it is because they present similar issues based on their dosage forms (*e.g.*, tablets and capsules), rather than “a desire to emulate drug CGMP requirements.”

As to FDA’s authority to inspect records relating to dietary supplement CGMPs, FDA stated that it requires such authority as a practical matter to make the CGMPs enforceable and asserted authority under its general “authority to promulgate regulations for the efficient

enforcement” of the Federal Food, Drug, and Cosmetic Act. FDA’s claim of authority to require access to dietary supplement CGMP records is contentious and is likely to be tested through litigation.

How We Can Help

Hunton & Williams’ Food & Drug Practice team assists clients in interpreting and complying with the Federal Food, Drug, and Cosmetic Act and regulations governing FDA-regulated products, including dietary supplements. We have experience in assisting clients with CGMP compliance and in interpreting the legal and regulatory framework governing dietary supplements under DSHEA. If you have any questions regarding the impact of the new dietary supplement CGMP regulations on your business, please contact us.

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