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FILE: · **Good Manufacturing Practices (GMPs)**
· **Quality Control**
· **Dietary Supplement Health and Education Act of 1994 (DSHEA)**

DATE: April 31, 1999 HC 091681

RE: New Quality Control Measures (GMPs) for Dietary Supplements

Boswell, C. Setting Quality Standards for Dietary Supplements. *Chemical Market Reporter Focus Report*, July 13, 1998, pp. FR 13 - FR 14.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) requires that FDA issue good manufacturing practices (GMPs) for the dietary supplements industry. While FDA progress toward GMPs has been slow, the Council for Responsible Nutrition (CRN), a trade association representing stakeholders in the supplement industry, drafted a set of GMPs in association with the American Herbal Products Association (APHA), and the Utah Natural Products Alliance (UNPA). This article proposes compliance guidelines on GMP's for the Dietary Supplement industry.

The FDA published the industry's draft of GMPs in February 1997 as an Advanced Notice of Proposed Rulemaking (ANPR). This ANPR included questions that lead many in the supplement industry to suspect the FDA intends to impose drug-like standards on dietary supplements. One such question was whether the GMPs should require that "reports of injuries or illnesses received by a firm be evaluated by competent medical authorities to determine whether follow-up action is necessary to protect public health." The industry modeled the proposed supplement GMPs on food GMPs and added additional controls over production, quality control records, sampling and testing of ingredients, and in–process materials. (Dietary Supplements are legally foods, not drugs and are, therefore, not required to meet stringent drug GMPs. Under DSHEA, the FDA may prescribe GMPs for dietary supplements and must model them after food GMPs and may not impose standards for which there is no current and generally available analytical methodology.)

While the comment period for the ANPR ended in June, the FDA has not progressed toward establishing final GMPs. Forouz Ertl, of Botanicals International, Long Beach, CA says the delay is due to a number of questions the FDA has, mainly concerning botanicals. There are no standards for

botanicals analogous to those used in the standardization of vitamins. To address this issue, Institute for Nutraceutical Advancement (INA), a Denver, CO based non-corporate analytical laboratory specializing in dietary supplement testing, formed the Method Validation Program (MVP) to establish standardized methods of analysis. Thirty companies financially support the program that submits analytical methods for eventual peer review by the Association of Official Analytical Chemists (AOFC). The method validations follow the AOAC peer-review protocol and upon completion are available to all laboratories through a variety of sources including ABC. The purpose of the MVP is not to create compulsory standards, but to eventually help assure consumers that the products they are buying is consistent from batch to batch.

The draft GMPs included input from all parts of the supplement industry. The proposed guidelines favor responsible manufacturers, and many smaller companies that are already following food GMPs will be able to meet the new requirements. According to this article many companies, such as Quality Botanical Ingredients Inc., South Plainfield, N.J., are voluntarily moving toward drug GMPs. They believe that informed consumers will prefer the higher quality standards.

One issue raised by Rod Lenoble, of Hauser Inc., Boulder, Colorado, concerns the demand that supplements meet 100 percent of label claims for the entire shelf life. Drugs are only expected to maintain 80 percent stability. Developing tests for the different components of blended products poses a difficult challenge. *—Leela Devi, MSN, RN*

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