How do Food and Drug Administration CGMPs for Dietary Supplements Affect Oriental Medicine Practitioners?

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Introduction

This article is designed to briefly address the history and regulatory impacts of recently adopted rules governing the manufacture of dietary supplements. Both the large scale manufacture of herbal products (and other supplements) and the compounding of individualized herbal formulations in small dispensary settings are covered by its regulations. Included in this article is the history of the regulation, a description of the concept of GMP or good manufacturing practice, an examination of what the Food and Drug Administration (FDA) regulates, and a brief discussion of the new regulation and how this impacts Oriental medicine practitioners.

Key Words: good manufacturing practices, Chinese herbal medicine, dietary supplements

In 2003 the Federal Food and Drug Administration presented proposed rules for current good manufacturing practices (CGMP) in manufacturing, packing, or holding dietary ingredients and dietary supplements. This rule was published in the Code of Federal Regulations (Title 21, Code of Federal Regulations, Parts 111 and 112, 2007) and addressed, in substantial detail, the methods or "process controls" that manufacturers or "holders" (businesses that hold dietary supplements or their ingredients during different stages of their manufacture) would need "to use to ensure that dietary supplement contains what the manufacturer intends" (21 CFR, Part 111, p. 34761, 2007). Because dietary supplements can range from something as simple as a tea bag containing spearmint leaves to a complex blend of vitamins, herbal extracts, and amino acid blended and sealed in a gel capsule, the rules are detailed and extensive. The initial rule, published in 2003, ran to 107 pages, after comment and revision. The final rule published in 2007 was 208 pages.

In its initial publication of the rule, the FDA stated "We decline to exempt herbalist practitioners from the proposed rule" (Federal Register, Vol. 68, No. 49, March 13, 2003 p. 12176). This determination alarmed the Oriental medicine professional community, as well as other professional herbalists, and comments were submitted by a number of Oriental medicine organizations and practitioners. Based on those comments and further analysis, the final rule included an extensive discussion of the issue (Federal Register, Vol. 72, No. 121, June 25, 2007 pp. 34793-4). The final rule makes it clear that the FDA has determined to exercise regulatory discretion in relation to this issue:

> *"We stated in the 2003 CGMP Proposal (68 FR 12157 at 12175) that we declined to exempt herbalist practitioners from the proposed rule. We continue to believe that the risks of adulteration are not eliminated just because the practitioner is an herbalist, and therefore, such an exemption should not be included in this final rule. However, after further consideration, we have determined that it would be appropriate for us to consider the exercise of our enforcement discretion in deciding whether to apply the requirements of this final rule to certain health care practitioners, such as herbalists, acupuncturists, naturopaths, and other related health care providers."* (Federal Register Vol. 72, No. 121, June 25, 2007 p. 34793)

The determination to "exercise enforcement discretion" was supported by the existence of what the FDA identified as "two potential safeguards:" "(1) Adequate training in the professional practice and (2) an individual client and practitioner relationship." On this basis the FDA suggests that an "herbalist" or "acupuncturist" who is adequately trained in the use of herbs and traditional Chinese medicines and is preparing these for use by an individual client with whom they have a practitioner relationship may not have the responsibility of meeting the requirements of the final rule: "We believe that a one-on-one consultation by a practitioner who is adequately trained in their profession may not necessitate the same types of controls as we are establishing in this final rule for manufacturing activities that are on a larger scale." While the statements in the final rule for CGMP should reassure Oriental medicine practitioners who conduct dispensary operations (herb pharmacies) in their clinics to provide for the needs of individual patients, the final rule on CGMP for dietary supplements does confront the practitioner with certain considerations.

What are GMPs?

As discussed, good manufacturing practice (GMP), or current good manufacturing practice (CGMP), refers specifically to practices in manufacturing that are "good" in the sense that they assure that the final product contains what the manufacturers says it contains, that it is hygienic, free of contaminants or adulterants and accurately labeled. Standards for GMP are typically developed by government agencies based on their legal authority.

Good manufacturing practices include a wide variety of methods for establishing quality control for every step of manufacturing ranging from acquiring and inspecting the ingredients to being able to recall defective or dangerous products. Some typical aspects of GMP include:

- validation of equipment & processes
- documented standard operating procedures for every part of manufacturing process
- log cleaning, calibration, etc.
- controlled environment, air, water
- isolation of raw materials and packaging
- reference specimens
- batch identification, batch records, reference materials
- post production product testing
- product tracking procedures
- recall procedures

Complaint and reaction records

Although good manufacturing practices in relation to herbal products seem like a new event, this is not the case. Dietary supplements produced in the United States have been required to conform to CGMP for foods, and those produced in other countries such as China, Japan, or Taiwan are required to be produced under strict GMP standards. More recently the standards of the Australian Therapeutic Goods Administration have been applied to Chinese herbal products manufactured for export to Australia. These standards, which require third party verification of production facilities, have come to be used as a kind of internationalized GMP that has become important in the marketing of Chinese herbal medicines in the United States.

What Does the FDA Regulate?

The Food and Drug Administration regulates the manufacture and distribution of food products, cosmetics, drugs, and medical devices where such items are part of interstate or international commerce. The FDA was formed in 1906 in response to serious problems related to the adulteration, safety, and mislabeling of food and drug products, and its regulatory authority has expanded over the years. In 1938, its authority was extended to cosmetics and therapeutic devices.

In 1994, congress passed the Dietary Supplement Health and Education Act (DSHEA). This act provided much needed clarity concerning the regulation of what were termed "dietary supplements." It established specific labeling requirements, provided a regulatory framework, and authorized FDA to promulgate good manufacturing practice regulations for dietary supplements. The Act defined "dietary supplements" and "dietary ingredients," classifying them as food. The definition of a dietary supplement was "a product taken by mouth that contains a "dietary ingredient" intended to supple-

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ment the diet." A dietary ingredient could include "vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites."

DSHEA placed "dietary supplements" in a special category under the general umbrella of foods, not drugs, and required that every supplement be labeled a dietary supplement. Many Oriental medicine professionals erroneously perceive dietary supplements as a special category that rescued herbs, herbal medicines, and traditional medicines from the challenge of fitting poorly into either category of food or drugs. This is not the case. Drugs are "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," and from this point of view most of the Chinese *materia medica* and the formulas prepared from them could be considered drugs. The fact that many prepared forms of Chinese formulas are in commerce as dietary supplements is due to the fact that they are appropriately labeled and that no drug claims are made for them.

Although a detailed discussion is beyond the scope of this article, it should be noted that the preparation or use of herbal products or supplements to treat disease shifts their use from that of a food or a supplement into the realm of a drug or medicine. It is this particular point that the FDA is commenting on when the commentary on the CGMP states "Many products that are manufactured by practitioners would not necessarily be considered to be dietary supplements (e.g., certain products used by traditional Asian medicine practitioners)" (Federal Register, Vol. 72, No. 121, June 25, 2007, p. 34793).

Finally, it is necessary to point out that the FDA does not regulate any aspect of the licensing or scope of practice of Oriental medicine practitioners. These activities are regulated by state law. However, the FDA does control products that are sold or distributed across state lines and imported into the United States.

What do the FDA CGMPs do?

Similar to the good manufacturing practices discussed above, the CGMP rules for manufacturers and holders of dietary supplements and dietary ingredients require that a manufacturer develop policy and procedures that meet that standards described by the rule and are appropriate for the type of product that is being produced. Critical features of the FDA CGMP include:

- Master Manufacturing Record
- Production & Process Controls
- Verification of Identity of Components
- Quality Control
- Product Complaints
- Record Keeping & Record Access
- Personnel
- Physical Plant & Grounds
- Equipment & Utensils
- Laboratory Operations
- Manufacturing Operations
- Packaging & Labeling Operations
- Holding & Distributing
- Returned Products

These features bring substantial clarity to the manufacturing standards and practices for dietary supplements and should serve to substantially protect consumers from mislabeled and adulterated products.

How do the FDA CGMP Regulations affect practice-based dispensaries?

FDA CGMP regulations affect practice-based dispensaries in a number of ways. The first and most important is that that both patients and practitioners have a greater assurance of the quality and safety of both traditional and proprietary Chinese herbal formula products sold as dietary supplements, assuming the manufacturer has complied with CGMP. The new standards provide greater assurance of product quality and the identity of the ingredients and allow practitioners to sell and recommend compliant products with greater confidence. This being said, it may now be incumbent, at least on a moral or ethical basis, on Oriental medicine practitioners to assure themselves that the products they recommend to their patients are compliant with the FDA CGMP.

Practitioners who compound and dispense mixtures of granular extracts of Chinese herbs and formulas, blend tinctures, prepare formulas from loose herbs and medicinal agents, prepare pills, poultices, or liniments, or repackage and label already manufactured pills need to consider several points: First, the FDA clearly considers all these activities be the manufacturing of dietary supplements and are subject to CGMP. Second, based on a recent systematic analysis of the feasibility of small scale dispensaries complying with the CGPM conducted on behalf of the Council of Colleges of Acupuncture and Oriental Medicine by members of the Council's herb committee, it is not possible for a small scale dispensary, or almost any dispensary "manufacturing" individualized formulas from loose herbs, to comply with these standards (Ergil & Wright 2009).

This being the case, Oriental medicine practitioners who do any of the activities described above need to rely on the standard provided by the FDA for its proposed enforcement discretion and engage in the manufacturing activities described above 1) on the basis of appropriate training, and 2) when they are preparing products (formulas, tinctures, poultices, etc.) which will be provided to patients on an individualized basis.

Beyond that, practitioners who compound and dispense might want to seriously consider implementing sanitary, recordkeeping, and dispensing practices that are realistic and economical in a private practice setting and that enhance the safety and well being of their patients.

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