

Herbalists' Options Under the FDA Final Rule for Current Good Manufacturing Practice for Dietary Supplements

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On June 25, 2007, the FDA published in the Federal Register the final rule entitled *Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements* (Docket No. 1996N-0417). The final rule takes effect 60 days after publication. Small businesses subject to the rule have three years to come into compliance.

The final rule for current good manufacturing practice (CGMP) includes requirements related to:

- * personnel and supervisory qualifications and hygienic practices
- * design and construction features of the physical plant
- * equipment and utensils
- * establishment of a production and process control system, including use of master manufacturing and batch production records
- * establishment of procedures for quality controls, including testing final product or incoming and in-process materials for identity, purity, strength, and composition
- * holding and distributing supplements and their components under appropriate temperature, humidity, light, and sanitation
- * procedures for handling returned products and consumer complaints
- * records and record keeping

Under the terms of the final rule, herbal practitioners who compound formulas for individual patients are considered to be manufacturers of dietary supplements engaged in interstate commerce, and therefore subject to the rule. However, the FDA states "...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" (p.156, pre-publication copy of final rule).

Note that considering the exercise of enforcement discretion is no guarantee of such discretion. Nor does it constitute exemption from the rule. Even if FDA initially chooses a policy of non-enforcement, it may quickly change that policy at any time by processes entirely internal to the FDA.

FDA regulations are drawn on by the courts to establish standards of practice. The new CGMP standards will become part of the evolving legal definition of the standard of herbal practice. The CGMP standards will be cited by judges and lawyers when things go awry and suits start flying. Thus it is unwise to ignore the rule in the belief that regulatory compliance is not necessary as long as it is not enforced by the FDA. Herbalists should begin to prepare now for the altered legal liabilities they will face in three years.

There are three options for herbalists to consider. The first option is to ignore the final rule and continue doing business as usual. The problems with this option have already been explained.

The second option is to bring the in-office herbal pharmacy into full CGMP compliance. For very small establishments, initial compliance (setup) costs are estimated at \$26,000, and annual compliance costs at \$46,000 (Table 35, pre-publication copy of final rule). For most herbalists, this option will not be financially viable. One modification is to formally petition FDA for some ingredient identity testing

exemptions, under the provisions of an interim final rule which will become effective in June, 2008 (<http://www.cfsan.fda.gov/~lrd/fr07625b.html>). While this will make compliance somewhat less expensive, it remains to be seen whether it can be a financially viable option. If this option is viable, patients can expect significant cost increases for custom herbal formulas.

The third option is to quit formulating and close the in-office compounding herbal pharmacy. Herbalists instead would fax individual patient herbal orders to a CGMP-compliant herbal pharmacy that will custom compound. This option is easily achievable, and it minimizes legal and regulatory liabilities. Yet it entails the separation of herbal prescribing from herbal formulating, and generates a windfall market gain for CGMP-compliant herbal formulators. As a direct result, patients will pay more for custom herbal formulas, and will experience greater delay in receiving them. By the FDA's calculations, the costs of the final rule will be about four times greater than the benefits (Tables 29 and 30, p716, pre-publication copy of final rule).

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