

FDA CGMP FOR DIETARY SUPPLEMENTS: FINAL RULE PUBLISHED ON 06/25/07

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On Monday, June 25, 2007, the FDA will publish in the Federal Register their final rule entitled Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (Docket No. 1996N-0417). The Final Rule will take effect 60 days after publication.

Compliance is expected within 12 months for firms with 500 or more employees. The compliance date is extended to 24 months for firms with 20 - 499 employees, and to 36 months for businesses with fewer than 20 employees. For very small establishments, initial compliance (setup) costs are now estimated at \$26,000, and annual compliance costs at \$46,000. (Table 35, pre-publication copy of final rule)

The Final Rule does not exempt individual herbalist practitioners or colleges that teach herbal medicine. 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)

That is to say, FDA will now have the authority to consider individual herbalists as manufacturers of dietary supplements. FDA may intervene with herbalists to enforce the final rule whenever it wants to. Considering the exercise of enforcement discretion is no guarantee of such discretion. No exemption from the rule has been granted to individual herbal practitioners.

The final rule and its supporting documentation run over 800 pages, with many changes to the proposed rule. Full assessment will take some time, and I will file a more comprehensive report at a later date.

David C. Kailin, Ph.D., M.P.H., L.Ac., is widely regarded as the leading authority on CAM-related federal regulations. He is the author of *Quality In Complementary & Alternative Medicine* (2006, CMS Press). Dr. Kailin provides consulting services on quality improvement and regulatory issues, and for integrative medicine programs. More information is available at <http://www.convergentmedical.com>