

FDA Proposed Rule for Good Manufacturing Practice for Dietary Supplements: An Update

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When a serious threat does not quickly and fully become manifest, it may gradually recede into the perceptual background, fading from memory while yet retaining all of its potential dangers. Such appears to be the case with regard to the Oriental medical profession's handling of a Food and Drug Administration (FDA) proposed rule that will re-define Current Good Manufacturing Practice (CGMP) for dietary supplements. If enacted as proposed, the rule will, by dint of its costs, effectively terminate the legal practice of in-office herbal compounding by individual practitioners. It is the most significant FDA action of the past two decades, in terms of its impacts on the practice of Oriental medicine. I will summarize the history and status of the proposed rule, and the Oriental medical profession's responses and options.

The proposed rule is entitled Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements.¹ It was first published in the Federal Register (68 FR 12157) on March 13, 2003, and a comment period was opened and extended to August 11, 2003. A copy of the proposed rule as published in the Federal Register is available at: <http://www.cfsan.fda.gov/~lrd/fr030313.html>.

Herbal practitioners who compound herbal remedies for individual patients would have to comply with stipulations covering:²

- * Personnel qualifications
- * Design of the physical plant
- * Equipment and utensils
- * Production and process quality control procedures
- * Holding and distributing
- * Handling of consumer complaints
- * Records of compliance

With respect to production and process quality control procedures, individual herbalists would be required to test final products to assure they met specifications of identity, purity, quality, strength, and composition. But if a scientifically valid analytic test did not exist, then herbalists would have to test incoming shipments of ingredients, and to test in-process, for any such specifications. Testing might involve organoleptic, microscopic, chemical, or other analyses. Some of these forms of testing are quite costly.

The stipulations (perhaps with significant modifications) could be implemented at higher levels of the herbal procurement and manufacturing systems. They cannot all be enacted at the level of very small entities such as individual practitioners. FDA estimates the first year cost of compliance for very small entities at \$62,000. This may be an unreasonably low estimate. Quite plainly, this cost cannot be borne by each individual herbal practitioner. The FDA impact statement fails to note this blatant fact, vastly underestimates the number of very small entities that would be impacted, and never considers the restriction of public access to herbal care that would result.³

Very few organizations and individuals representing the Oriental medical community responded to the FDA request for comments. Their comments tended to be similar, very brief, and offered near the end of the comment period. It seems that, until the last moment, members of the community were unaware that the proposed rule defined individual herbal practitioners as manufacturers of dietary supplements.

However, this provision was clearly stated in the original publication in the Federal Register.⁴ Our national and state associations apparently failed to detect this at an early enough date to permit the development of more substantive responses.

After the close of the comment period, an alliance of Oriental medical and herbal associations gathered under the rubric of the Traditional Medicines Congress. In November of 2005, they produced a draft of an ideal regulatory model for traditional medicines.⁵ The proposal and enactment of a new regulatory framework is a very ambitious long-term project, and not without merit. But it is not a direct, timely, and effective way to achieve the exemption of individual herbalists from the FDA proposed rule. Oriental medical associations have also campaigned against restriction of herbs containing ephedrine alkaloids.⁶ Direct action on the proposed rule for CGMP on behalf of the Oriental medical community has been conspicuously absent.

Many *bona fide* manufacturers of dietary supplements did respond to the FDA during the comment period, and in great depth. I do not recall (after a cursory review) that any of them spoke to the negative effects of the proposed rule on individual herbal practitioners, though there might have been a few supportive comments. It is conceivable that the large manufacturers of dietary supplements would like their products to supplant those compounded in the office by individual herbalists. The lesson for the future is to select allies among manufacturers based on common interests as substantiated in the comments that were submitted to the FDA. You can access all of the comments, located in docket 96n0417, at: www.fda.gov/ohrms/dockets/dockets/96n0417/96n0417.htm.

Because the proposed rule is deemed a major rule, it must go through several review processes. On Oct. 25, 2005, the FDA delivered the proposed rule to the Office of Management and Budget (OMB), where it rests as of this date (3/13/07). OMB reviews the proposed rule for fiscal and other impacts, and shares its concerns with FDA. FDA may make amendments, and then will publish the final rule in the Federal Register. Under the Congressional Review Act, Congress has 60 in-session days to review (and possibly reject) the final rule. The General Accounting Office will also provide a review to Congress.

To reject the final rule, a simple majority vote of the House and Senate (and the President's signature, if passed by both chambers) would decide a Resolution of Disapproval. In the last decade, only one agency final rule has been rejected in this way by Congress and the President. Rejection of the final rule can be done, but it is not easy to accomplish.

Why has the proposed rule not been reported out of OMB for over a year? OMB is an executive branch agency, and its actions (and inactions) can reflect the interests of the White House. Perhaps the White House objects in principle to the imposition of new costs and constraints that would be borne by manufacturers. Yet OMB's inaction provides only a temporary stay, and one that will not make the proposed rule disappear.

With the mid-term elections, there has been a palpable power shift in Washington. The White House is now in the position of having to bargain with the Democratic-controlled Congress. At any time now, a little Washington horse-trading could lead OMB to release the proposed rule. I have not ascertained Republican Party and Democratic Party intentions with respect to the proposed rule.

No one can currently say whether the final rule will include or exempt individual herbal practitioners. (One consultant with close ties to the FDA recently let me know that she is unaware of any move to exempt herbalists.) What should the Oriental medicine community do, given that the potential consequences are so considerable? To do no more than prepare for compliance with the proposed rule is a passive and fatalistic response.

The first course of action for Oriental medical organizations is to lobby OMB, and to request particular members of Congress to bring their concerns to OMB. (OMB does respond to Congressional inquiries.) The focal concern is exemption of individual herbal practitioners. This effort should be well-coordinated and swift.

A second course of action for Oriental medical organizations is to lobby Congress, even before the final rule is published. We must provide a convincing picture of negative economic, social, and medical impacts on very small entities and the public, if individual herbal practitioners are not exempted. We would be well served by cogent arguments for the effectiveness of quality controls at higher levels of the herbal procurement and manufacturing systems. It is time to develop the groundwork for Congressional and Presidential rejection of the proposed rule.

As a third course of action, we should identify and approach organizations outside the Oriental medical community with whom we share common interests on this issue. We should approach them now and develop coordinated plans.

A fourth course of action, to be taken only if the final rule does not exempt individual herbal practitioners, is to mobilize grass roots support from patients and the public. This typically involves a campaign of calls or emails to members of Congress from constituents.

The Oriental medical profession was late in commenting on the proposed rule, and is late again in developing and implementing strategies to amend or defeat the final CGMP rule. The newly re-united national association and all its members are encouraged to recognize the high priority of the problem, to consider the options, and then to implement well-focused responses.

CITATIONS

1. Dept. of Health and Human Services, Food and Drug Administration. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements. *Federal Register*, Volume 68, Number 49, March 13, 2003. Pages 12157-12263.
2. *ibid*, page 12164
3. *ibid*, page 12242-5
4. *ibid*, pages 12175-7
5. Traditional Medicines Congress. *A Proposed Regulatory Model for Traditional Medicines: Guiding Assumptions and Key Components*. 2005. www.traditionalmedicinescongress.com/proposal
6. AAOM. *AAOM Herbal Medicine Committee (HMC) Call to Action*. AAOM Press Room, Herbal Updates. 2005. www.aaom.org/45200.asp

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