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AAAOM Comments on FDA Rule

Editorial Staff

In the wake of the June release of the FDA's current Good Manufacturing Practices (cGMP) for Dietary Supplements, the AAAOM has been compiling a detailed analysis of what this rule will really mean to practitioners, educators, students and patients of acupuncture and Oriental medicine. On Sept. 13, 2007, it released a summary analysis with several key points for consideration. The AAAOM hopes to have the full analysis up on its Web site (www.aaaomonline.org) shortly.

In the introduction to the summary, AAAOM President Leslie McGee, LAc, noted, "When the Proposed Rule came out in March 2003, both the Acupuncture and Oriental Medicine Alliance ("Alliance") and the American Association of Oriental Medicine ("AAOM") submitted comments to the FDA to assure that the unique training of AOM practitioners and the specialized use of traditional Chinese herbs were appropriately addressed in the regulations. In the four years between the issuance of the proposed and final rules, the FDA received hundreds of comments, and revised the proposed rules based on the information that was received."

The text of the summary reads as follows:

Key Points From the AAAOM Analysis of the FDA's Final Rule on Current Good Manufacturing Practices for Dietary Supplements

- A practitioner whose only involvement with dietary supplements is that the practitioner purchases herbal formulas which are packaged and labeled as dietary supplements and resells these products to the practitioner's patients for consumption in a course of treatment is exempt from the Final Rule.

The Final Rule says in §111.1(a) that the Final Rule only applies to you "...if you manufacture, package, label or hold a dietary supplement." In the example above, the practitioner is not manufacturing, packaging or labeling dietary supplements. The practitioner's only connection with the Final Rule is holding dietary supplements pending sale to patients. The Final Rule then goes on to say in §111.1(b) that the "...requirements pertaining to holding do not apply to you if you are holding those dietary supplements at a retail establishment for the sole purpose of direct sale to consumers." The preamble to the Final Rule explains that "retail establishment" includes not just an herb shop and a health food store, but also includes an individual, such as the practitioner in our example. Consequently, the practitioner in the example above is exempt from the Final Rule.

There are limitations on the retail establishment exemption, but they should not be a problem for most practitioners. To be eligible for the exemption the practitioner cannot store the dietary supplements in a warehouse or other storage facility or sell directly from a warehouse.

- A practitioner who maintains an herbal pharmacy and prepares herbal formulas for patients based on their individual needs is not exempt from the Final Rule.

According to the Final Rule, a practitioner who prepares herbal formulas may be engaged in

manufacturing, as defined by the FDA, and consequently subject to the Final Rule, if what the practitioner is manufacturing is a dietary supplement.

While declining to exempt herbalists from the Final Rule, FDA did say in the preamble to the Rule that it might exercise its enforcement discretion in favor of "herbalists, acupuncturists, naturopaths and related health care providers" under certain circumstances. FDA explained that a "one-on-one consultation by a practitioner adequately trained in their profession may not necessitate the same type of controls as we are establishing in this final rule for manufacturing activities on a larger scale." FDA concluded, "We believe that it would be appropriate to consider the exercise of our enforcement discretion, on a case-by-case basis, to determine whether to apply the requirements of the final rule to such persons."

The FDA is retaining its right to enforce the requirements, while also saying it will consider not enforcing the requirements against these practitioners. While we would prefer that qualified practitioners were fully exempt in these situations, we understand that without any clear guidance distinguishing small from large scale manufacturers, it would be difficult to grant such an exemption.

- The FDA states that "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)." These products would not be subject to the Final Rules.

To the extent that these formulas are not dietary supplements, the Final Rule does not apply to them. Yet, current law does not delineate which herbal products are considered to be dietary supplements are which are not in this category. The AAAOM plans to do further work in this area.

- The Final Rule does not take effect until June 2010 for persons employing fewer than 20 employees.

This category should include most practitioners, so there is time to discuss and plan for any action needed.

- Academic institutions are not exempt from the Final Rule.

While declining to exempt academic institutions, FDA did say it is not its policy to inspect academic institutions providing training for therapeutic disciplines that use dietary supplements in their practice. In addition FDA would consider using its enforcement discretion in situations where dietary supplements are dispensed after one-on-one consultation which includes a practitioner with adequate training. FDA intends to issue further guidance in this area.

Link to the Final Rule: More information will follow as it becomes available. The regulation can be viewed at www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm. Enter docket number "96N-0417" in the search field. You may also visit the FDA website at www.fda.gov.

Link to provide comments: www.aaaomonline.org/interactive.asp?ID=22.