American Medical Association
Physicians dedicated to the health of America

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements [Docket No. 96N-0417]

The American Medical Association (AMA), the largest national professional association representing physicians and physicians-in-training, commends the Food and Drug Administration for issuing its proposed regulation on current good manufacturing practice (CGMP) for dietary ingredients and dietary supplements. The AMA believes this proposed regulation is an excellent first step toward improving the overall regulation of dietary supplement products.

On numerous occasions, the AMA has expressed its concerns to the FDA regarding the quality, efficacy, and safety of dietary supplement products. By requiring manufacturers to evaluate the identity, purity, strength, and composition of their dietary ingredients and dietary supplements, this CGMP regulation should provide consumers with some assurances that the dietary supplement product contains the ingredient(s) listed on the product's label and that the product is not adulterated. Thus, consumers should have greater confidence in the quality of dietary supplement products and, to a more limited degree, in their safety. Unfortunately, this proposed regulation does not address concerns about efficacy or adverse events that are unrelated to good manufacturing practices.

The AMA is pleased that the FDA is proposing that dietary supplement manufacturers be required to review and keep a record of all consumer complaints related to CGMP (Subpart G). Furthermore, the AMA supports the proposal that manufacturers must have their quality control units investigate those consumer complaints when there is a reasonable possibility of a relationship between the quality of the dietary supplement and an adverse event. The AMA believes this should be extended to any possible relationship between a dietary supplement and an adverse event, including those that may be independent of whether the product is produced under good manufacturing practices.

Finally, the AMA recommends that the FDA designate the United States Pharmacopeia (USP) to develop appropriate standards for the identity, purity, strength, and composition of dietary ingredients and dietary supplements. The USP has an extensive track record, dating back to 1820, for developing such quality standards for drugs and is officially

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recognized by the United States government. Thus, the USP would be the ideal body to develop quality standards for dietary supplements.

In conclusion, the AMA believes the FDA should move toward a final rule on CGMP for dietary ingredients and dietary supplements as quickly as possible. We appreciate your consideration of our recommendations to improve this regulation.

Sincerely,

Michael D. Maves, MD, MBA