**THE AMERICAN DIETETIC ASSOCIATION**
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Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., rm. 1-23
Rockville, MD 20857

RE: FDA Docket No. 96N-0417

**The Comments of the American Dietetic Association in response to the Food and Drug Administration's (FDA's) request for comments as published in the February 6, 1997 Federal Register, Vol. 62, No. 25: Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements: Advance notice of proposed rulemaking.**

The American Dietetic Association (ADA) represents nearly 70,000 food and nutrition professionals serving the public through the promotion of optimal nutritional health and well being. The ADA appreciates having the opportunity to submit comments in response to the Food and Drug Administration's (FDA's) advance notice of proposed rulemaking (ANPR) on **Current Good Manufacturing Practice (CGMP) in Manufacturing, Packing, or Holding Dietary Supplements** and commends FDA for their efforts in evaluating the need for regulations in this area.

The ANPR asks for comments in two general areas: first, is there a need for CGMP regulations in the dietary supplement arena; and, second, if such regulations were developed, what specific areas should be covered.

Regarding the first issue as to whether FDA should promulgate CGMP regulations for dietary supplements, ADA strongly supports the need for regulations that specify CGMP for the manufacturing, packing, and holding of dietary supplements. Furthermore, ADA concurs that such regulations should be no less specific than those currently in place for foods. ADA believes that the proliferation of dietary supplements available to the public in numerous outlets (including grocery stores, health care/food stores, and mail-order catalogs), and the unique nature of these products, justify the need for close examination of regulatory standards and procedures.

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ADA members feel strongly that the broad number of products defined as dietary supplements under the Dietary Supplement Health and Education Act (DSHEA) requires the need for the promulgation of specific CGMP regulations. The public should, at a minimum, have access to dietary supplements produced under conditions comparable to those required for food.

While ADA is not prepared to comment on the specifics of the ANPR at this point, we do plan to comment on any rules prepared by FDA in this important area.

Sincerely,

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