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

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

Dear Food and Drug Administrators:

This is American Laboratories, Incorporated (ALI) introductory letter identifying our recommendation for modification of the United States Food and Drug Administration (FDA) proposed 21 CFR Part 111 regulations. Our intentions are to constructively provide a practical and cost effective route of obtaining and maintaining a safe dietary supplement industry. Please accept our suggestions in that mode.

ALI is an FDA registered manufacturer of bulk domestic animal based thyroid products and United States Department of Agriculture (USDA) registered domestic animal derived dried meat products. ALI also manufactures bulk food grade enzymes and dried glandulars, that could be classified as dietary ingredients, with a collective 36-year history of safely and successfully producing and distributing these bulk products.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) established the guidelines and rationale for the regulations proposed in the United States (US) Food and Drug Administration (FDA) 21 CFR Part 111 (21CFR111). As stated in the October 25, 1994 Act:

> "Congress's intent in enacting the DSHEA was to meet the concerns of consumers and manufacturers to help ensure that safe and appropriately labeled products remain available to those who want to use them. –Congress stated that there may be a positive relationship between sound dietary practice and good health, and that, although further scientific research is needed, there may be a connection between dietary supplement use, reduced health-care expenses, and disease prevention."

However, DSHEA redefines the term "dietary supplement" to products including previously approved new drugs, certified antibiotics, or licensed biologics. Therefore, the dietary supplement industry has been forced to consider FDA attempts to apply current good manufacturing drug practices (cGMP) and Hazard Analysis and Critical Control Point (HACCP) regulations specified in 21CFR111. Moreover, 21CFR111 embraces the suggestion of including the Center for Biologics Evaluation and Research CBER) guidances 50244 and 51074 for viral clearance procedures for human cell-lines and their products into regulations covering the manufacturing of animal derived dietary supplements. These suggestions stray from Congress's intent, because they virtually reclassify dietary supplements to substances and practices that are not applicable, relevant, or cost effective in "ensuring that safe and appropriately labeled dietary supplements remain available to those who want them"!

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FDA 21 CFR Part 111 Proposed Regulation Changes

We concur with the leading members in our industry and the Council for Responsible Nutrition (CRN) that regulations have existed for decades in 21 CFR Part 110 that covers dietary ingredients and dietary supplements. Moreover, a careful consideration of these existing regulations including the DSHEA act provides clear evidence that all examples of infractions cited in the preamble of 21CFR111 could and have in the past been successfully dealt with under these regulations. Since DSHEA nor 21CFR111 do not define "dietary ingredient", ALI again agrees with our industry representatives and CRN that dietary ingredients should be excluded from inclusion in 21CFR111. Dietary ingredients are components of conventional foods, animal feeds, and pet foods as well as non-food or drug products and are successfully regulated under 21 CFR 110. A component does not become a dietary ingredient until it is incorporated into a dietary supplement, which further supports the premise that bulk dietary ingredient manufacturers should be covered under general food good manufacturing practices (GMPs) as is currently the case. There also appears to be some question as to the authority FDA has in proposing new laws governing dietary ingredients.

The dietary supplement industry has long been in compliance with general food GMPs and has demonstrated this fact by having only 43 recalls for non-declared ingredients or microorganism contamination between 1990 and 1999. As quoted by the CRN as well, the FDA website has shown that there were 975 drug recalls and 1450 conventional food recalls during this same period. History demonstrates that new regulations do not make for less recalls nor do they eliminate "human error". Good training and controlled processes achieve these goals and ALI and the industry have proven that by their track record in successfully manufacturing, packaging, labeling, and distributing high quality and safe dietary supplements. Furthermore, microorganism product contamination and plant sanitary conditions have been regulated successfully and have been a major part of the track record of the lowest number of product recalls in our related industries. Vendor qualification programs with testing-based Certificates of Analysis have been other time-tested corner stones of this industry and should be allowed and supported in 21CFR111. Exhaustive testing of ingredients and final products will not eliminate human error but will significantly drive up the cost of producing the dietary supplement in direct contrast to Congress's stated intention in DSHEA (see earlier quotation). Also, all foreign suppliers and manufacturers of dietary ingredient and dietary supplements should be required to comply with the same regulations promulgated upon domestic manufactures. ALI agrees with the FDA in not requiring shelf-life dating of dietary ingredients and dietary supplements that exerts more significant production costs.

In summary ALI's response to proposed 21CFR111 regulations is an effort to revise those proposals to retain a "food classification" and enhance the safety and effectiveness of dietary ingredients and dietary supplements. These new regulations do not have to redefine existing and successful general food GMPs, nor the industries' products or their nature, and therein add unnecessary production costs forcing their pricing beyond the reach "of those who want to use them". ALI has organized these modifications according to the section numbers and titles given in 21CFR111 proposed regulations as well as adding a significant review of the literature on bovine spongiform encephalopathy (BSE) justifying the elimination of CBER guidances 50244 and 51074 inclusion in 21CFR111.

Sincerely yours,

Allen L. Asherin
Vice President of Regulatory Affairs

Kenneth H. Kortright, Ph.D.
Assistant to the President

AMERICAN LABORATORIES INCORPORATED RESPONSE TO PROPOSED FEDERAL REGULATIONS 21 CFR PART 111

By Dr. Kenneth H. Kortright & Allen L. Asherin
American Laboratories, Incorporated **08/06/2003**

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