February 14, 2001

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 c **St. SW** Washington DC 20204

Re: <u>Notification of DSHEA nutritional support claim for AmeriFIT Flex Able Chewables Dietary</u> <u>Supplement</u>

Dear Sir or Madam:

The purpose of this letter is to provide notification pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act ("the Act") and 7 C.F.R. § 101.93 that AmeriFIT, Inc., is marketing a dietary supplement that bears a statement of nutritional support as defined in section 403 (r)(6) of the Act.

The labeling for Flex Able Chewables bears the following statements:

"Flex Able"

"... promote healthy joints, tissue and flexibility"

="Glucosamine helps build cartilage to maintain range of motion and joint flexibility. A natural substance noted to play a role in the health and resiliency of joints"

"Chondroitin sulfate is a vital, natural compound to support ease of movement by lubricating joint embranes. (Gelatin) is au excellent protein source that helps maintain joint connective tissue"

"Glucosamine . . . plays an important role in the health and resiliency of joints and cartilage . . ."

"... can help support normal joint tissue functioning"

"Chondroitin is a vital compound in connective tissue that is partly responsible for building and supporting the basic substance of cartilage . . . helps attract and hold water, which aids in keeping your joint membranes fluidized . . . (and can) assist(s) with joint mobility and range of motion . . ."

AmeriFIT, Inc. has on file substantiation that the above statements are truthful and not misleading. To the best of my knowledge, the information contained in this notice is complete and accurate.

Sincerely,

Craig Larsen Director of Product Integrity

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