

# Amerifit<sup>TM</sup> NUTRITION

August 21, 2002

DEC 03 2002

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: Notification of DSHEA nutritional support claim for AmeriFIT Estroven Dietary Supplement

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 Estroven® bears the following statements:

"Naturally Helps Support Hormonal Balance"

"... sources of natural plant estrogens, for hormonal balance"

"... for a healthy heart"

"Calcium for healthy bones"

"... relief of irritability and help you get a good night's sleep"

"... which work with the body to help support hormonal balance ..."

"... act like your body's own and help provide a natural hormone balance"

"Estroven is a good source of supplemental calcium, as well as boron, a mineral which aids calcium absorption"

"Vitamin E ... is a key antioxidant, protecting your body from pollutants"

"(Black Cohosh) has been used ... to provide support for many areas of female health"

"... herbs used to reduce irritability and support a good night's sleep ..."

"(B-Vitamins) are essential to transform carbohydrates into energy"

"Estroven provides balancing levels of natural nutrients ..."

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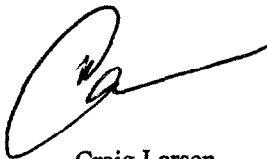
The package insert for Estroven® also provides information on other Amerifit Nutrition products, and as such, the statements for those products are included in this submission:

“... for maintaining flexible joints today and building strong bones for tomorrow.” (referring to Estroven Joint and Bone)

“to help stimulate, strengthen and build your body’s natural defenses.” (referring to Sootherbs Liposome Zinc)

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,

A handwritten signature in black ink, appearing to read 'Craig Larsen', with a long horizontal flourish extending to the right.

Craig Larsen  
Director of Product Integrity