

AmeriFitTM NUTRITION

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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

FEB 21 2001

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"

"Kava kava to reduce 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. . . th provide support for many areas of female health"

"(Kava Kava) This traditional calming herb . . ."

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

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

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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