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March 26, 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: <u>Notification of DSHEA nutritional support claim for AmeriFIT ESTROVEN PMS 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 bears the following statements:

"Control Emotional & Physical Symptoms of PMS"

"Irritability Moodiness Cramps Bloating"

"Estroven PMS .... shown to manage the symptoms of PMS ....."

"... to reduce irritability and moodiness"

"... to reduce bloating and cramping"

"... to help reduce discomfort"

"... to help support hormonal balance"

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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