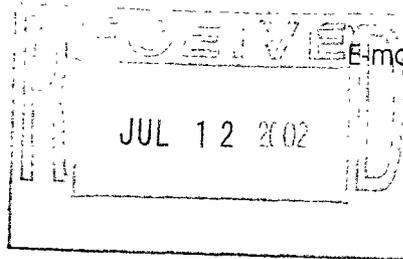




470 Route 9  
Englishtown, NJ 07726

Tel: 732-617-1100  
Fax: 732-536-9179  
E-mail: edgelabs@aol.com



6/13/02

Office of Nutritional Products, Labeling and  
Dietary Supplements (HFS-800)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

**SECTION 403(r)(6) NOTIFICATION**

RE: **SOY FOR HEART**

Dear Sir or Madam:

In accordance with the requirements of section 403 (r)(6) of the Federal Food, Drug and Cosmetic Act, EDGE LABS INC. notifies FDA that it has begun using the following statements regarding soy protein and the B vitamins B6, B12 and folic acid:

**“Two servings of Soy for Heart, as part of a diet low in saturated fat and cholesterol, supply the 25 grams of soy protein that, if taken daily, may reduce the risk of heart disease.”**

**“Homocysteine build up has been associated with an increased risk of heart disease.”**

**“Vitamins B6, B12 and Folic Acid have been linked with reducing levels of homocysteine in the blood.”**

**“Soy is a rich source of isoflavones and saponins, naturally occurring plant antioxidants that have shown a positive effect on heart health.”**

Which contain the statutory statement, on the following product:

**SOY FOR HEART**

I certify that the foregoing is complete and accurate, and that EDGE LABS has substantiation that the statements are truthful and not misleading.

Very truly yours,

  
EDGE LABS INC.  
By Sandy Filippone

975 0162

LET 10456

Also see docket 975-0163

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