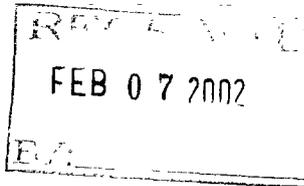


3589 02 FEB 19 2:23

January 25, 2002

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



RE: SECTION 403(r)(6) NOTIFICATION

Dear Sir or Madam:

In accordance with the requirements of Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, Unither Pharma, Inc. notifies FDA that it has begun using the following sets of statements, each of which contains the statutory statement, on the labels of the products indicated below. All of the statements are based on the presence of L-arginine in the respective product(s):

1. **“Improves endurance, circulation, and energy.”**

“Dietary Supplement for Heart Health, Energy and Vitality.”

The foregoing statements were used on the following products:

HeartBar® Sport Dietary Supplement Orange Flavored Mix jar and box and

HeartBar® Sport Dietary Supplement Bars (cranberry flavored, cranberry flavored with yogurt flavored coating, original/vanilla flavored, original/vanilla flavored with milk chocolate flavored coating, peanut butter flavored, and peanut butter flavored with milk chocolate flavored coating)

2. **“Clinically proven results.”**

“Do your heart good with HeartBar® Sport dietary supplement.”

Unither Pharmaceuticals, Inc. • 1077 Hwy A1A • Satellite Beach, FL 32937 U.S.A.
(321) 676-0010 • Fax (321) 676-2282

www.unitherpharma.com

975 0162

LET 9325

“Based on the science that won the 1998 Nobel Prize in medicine, HeartBar® Sport contains a patented formula with L-arginine to encourage dilation of blood vessels and smoother blood flow.”

“If you are concerned about heart health, adding HeartBar® Sport to your diet provides clinically proven benefits.”

“HeartBar® Sport improves circulation and energy to help you lead a more active lifestyle and get the most out of your fitness regimen.”

The foregoing statements were used on the following products:

HeartBar® Sport Dietary Supplement Orange Flavored Mix box and

HeartBar® Sport Dietary Supplement Bars (cranberry flavored, cranberry flavored with yogurt flavored coating, original/vanilla flavored, original/vanilla flavored with milk chocolate flavored coating, peanut butter flavored, and peanut butter flavored with milk chocolate flavored coating)

3. “Clinically Proven Results Based on 1998 Nobel Prize-Winning Science.”

The foregoing statement was used on the following product:

HeartBar® Sport Dietary Supplement Orange Flavored Mix jar

I certify that the foregoing is complete and accurate, and that Unither Pharma, Inc. has substantiation that the statements are truthful and not misleading.

Very truly yours,



Barry Kanarek, Ph.D., MD
President and COO
Unither Pharma, Inc.