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BY: \_\_\_\_\_

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

Re: Label claims made for nutritional product

August 23, 2001

Ladies/Gentleman:

This letter notifies the Food and Drug Administration that within the past 30 days our company has begun to market Male Advantage™ [Dietary] Supplement, with the following statement of nutritional support included on the label and in labeling for the product:

“Male Advantage™ helps support a healthy prostate, cardiovascular system, and overall male health.”

The dietary ingredients of the product that are the subject of the above statement are: saw palmetto berry fruit extract, kava kava, flax seed, pumpkin seed, Korean ginseng root, Siberian ginseng root, turmeric, bromelain, pygeum africana bark wet extract, damiana leaf, L-alanine, L-glutamic acid, and gotu kola whole plant.

It is hereby certified that the information in this notification is complete and accurate, and that our company has substantiation that the above statement is truthful and not misleading.

Very truly yours,

Body Wise International  
Juliana Tinkelenberg  
Director of Communications

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