

June 24, 2002

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810) Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740



Re: Notification for Statements on Dietary Supplement Labels

Dear Sir/Madam:

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. §343(r)(6), and in accordance with the authorized provisions of 21 CFR §101.93(a), your Agency is hereby notified that Renaissance Herbs, Inc. has made the following statements of "nutritional support", as described in 21 U.S.C. §343(r)(6)(A), for its Ayurceutics line of dietary supplements as follows:

Product Name	Label Statement
Pegasus™ Standardized Ashwagandha, 5% withanolides	 Stress and mental stamina. Helps to manage normal daily stress. Supports health brain function.
BosWell™ Standardized Boswellia, 85% boswellic acids	Supports healthy joint function.
Gymulin™ Standardized Gymnema, 75% gymnemic acids, 35% gymnemagenin	 Helps to maintain blood sugar levels that are already within the normal range. Supports healthy function of the pancreas.
TriBull™ Standardized Tribulus terrestris, 60% saponins	 Increases libido. Improves sexual performance.
Triphala Standardized Triphala, 50% tannins	Traditional Ayurvedic herbs for digestion and purification.

I certify that the information contained in this notice is complete and accurate, and that Renaissance Herbs, Inc. has substantiation that the statements are truthful and not misleading.

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LET 10385 Alex Moffett Founder & President Renaissance Herbs