

INCORPORATED

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www.usninc.com Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, SW Washington, DC 20204

Re: Notification of Statements on Dietary Supplement Labels

Pursuant to 21 C.F.R. § 101.93, World Nutrition, Inc., the manufacturer and distributor of Vitalzym, hereby notifies the Food and Drug Administration (FDA) that it is using the following statements on the label and in the labeling of Vitälzym, which contains a proprietary enzyme blend of protease, serrapeptase, papain, bromelain, amylase, lipase, rutin, and amla:

- Enzymes are needed for each biochemical reaction that makes life possible. They initiate millions of reactions in your body. Without enzymes, life could not exist.
- Supplementation with Vitälzym along with proper diet and exercise will help to normalize your enzyme levels, balancing your bodies own repair mechanisms.
- Vitälzym may assist the body with:

Fibrin: Normal enzyme levels help guard against the formation of fibrin.

Blood: Enzymes help cleanse the blood of debris, maintaining blood

health.

Immune Function: Enzymes help maintain healthy immune systems. Healthy Circulation: Normal enzyme levels help promote healthy blood circulation.

In accordance with 21 C.F.R. § 101.93, the above statements are accompanied by a prominent disclaimer. The information contained in this notice is complete and accurate, and World Nutrition has substantiation that these statements are truthful and not misleading.

As required, the original and two copies of this notification are enclosed.

Sincerely,

State 10 218 Patrick Buehl

Vice-President

World Nutrition, Inc.

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