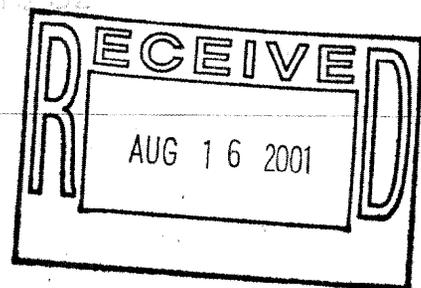




Whole Food Supplements

August 8, 2001

1006 '01 AUG 20 P2:52



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

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

1. Livaplex is primarily a liver support product that works to promote healthy enzyme production in the liver.
2. These enzymes help the body naturally convert potentially harmful substances into less toxic compounds.
3. Healthy liver function breaks down toxins to promote healthy blood flow.

These statements are made for a dietary supplement containing a proprietary blend of bovine liver PMG™ extract, spanish black radish (root), bovine liver, calcium lactate, beet (root), carrot (root), *Tillandsia usneoides*, dried beet (leaf) juice, betaine hydrochloride, magnesium citrate, choline bitartrate, soy (bean), oat flour, bovine kidney, bovine prostate, bovine adrenal Cytosol™ extract, defatted wheat (germ), bovine liver fat extract, bovine orchic extract, ascorbic acid, flaxseed oil extract, and mixed tocopherols. Other ingredients include gelatin, zinc liver chelate, iron liver chelate, water, potassium bicarbonate, calcium stearate, niacinamide, copper liver chelate, natural colors, pyridoxine hydrochloride, vitamin A palmitate, and prolamine iodine (zein). The name of the product is Livaplex®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

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