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February 20, 1999



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) Echinacea helps white blood cells to engulf microscopic invaders. Echinacea supports the immune system, specifically non-specific cellular immunity, by helping various types of white blood cells in phagocytosis, the process by which they engulf, destroy, and mop up unwanted organisms or defective host cells. Echinacea stimulates an increase in the sheer numbers of neutrophils, the body's prime engulfing white blood cell. It also increases the phagocytic activity of macrophages, polymorphonuclear neutrophil granulocytes, natural killer cells.*

(2) Echinacea may stimulate redness, swelling and increased body temperature - powerful weapons against microscopic invaders. In the laboratory echinacea has been shown to stimulate the release of powerful immune controllers called cytokines, substances that initiate and control many aspects of the immune response, including redness, swelling and increased body temperature.*

(3) In the face of microscopic invaders, echinacea maintains normal connective tissue by inhibiting hyaluronidase. The polysaccharides in echinacea are believed to inhibit hyaluronidase *

(4) Recent studies suggest that echinacea is a safe seasonal protector.*

(5) Vitamin C maintains normal immune function in the face of physical and environmental stress. It protects leukocytes against their own poisons they emit in their immune functioning.*

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These statements are made for a dietary supplement containing echinacea root powder, acerola powder, rose hip powder, vacuum dried buckwheat juice and seed, honey, and calcium stearate. The name of the product is Echinacea-C™.

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.

