



1148 '99 NOV 15 P3:19



October 25, 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) Inositol, found in the membranes surrounding each cell, plays a key role in the body's complex internal communication system. It is required to transfer the body's chemical orders from the blood stream to the inside of the cell where they can be filled.
- (2) Inositol migrates inside the cell to trigger a multitude of specific functions, which include secretion of digestive juices and histamine, muscle contraction, glucose production, and clotting assistance.
- (3) Brain and central nervous system tissues contain relatively high amounts of inositol, which may help maintain mental well-being.
- (4) Inositol maintains mental health.
- (5) Inositol may be involved in regulating the key neurotransmitter serotonin. Inositol supplements can actually lower the pool of inositol in one part of the brain, most likely through a feedback mechanism. Small-scale studies suggest inositol helps maintain a more consistent and even emotional mood. Other studies have found inositol supplementation helps people moderate emotional response to sudden life changes.
- (6) Inositol promotes normal fetal neural tube development.
- (7) Inositol supports normal infant central nervous system and lung system development.
- (8) Inositol helps keep your colon healthy.

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These statements are made for a dietary supplement containing inositol, honey, and calcium stearate. The name of the product is Inositol.

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

Sincerely yours,

A handwritten signature in cursive script that reads 'Ann M. Holden'.

Ann Holden
Standard Process Inc.

