



**Standard
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October 25, 1999

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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) Calsol promotes women's health.
- (2) Research suggests that women who take in adequate amounts of calcium throughout their lives greatly reduce their risk of excessive bone loss later in life. Optimal calcium intake can also reduce cyclical discomfort by helping to maintain the normal functioning of the parathyroid hormone.
- (3) Calsol maintains normal nerve functioning.
- (4) Calcium is essential to the normal transmission of nerve impulses.
- (5) Calsol keeps your heart healthy.
- (6) The heart requires phosphorus to continue regular heart muscle contractions. Calcium helps maintain regular heart rhythm and also helps to maintain healthy cholesterol levels in the bloodstream.
- (7) Calsol maintains cellular health.
- (8) Calcium helps the walls of the cells to remain porous so that substances are able to come in and go out of cells easily.
- (9) Calsol supports kidney function.
- (10) Phosphorus is needed for proper kidney function.

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- (11) Calsol supports metabolic processes.
- (12) Calcium supplies energy and is involved in activating many enzymes necessary for breaking down fats for the body. Phosphorus helps the body use vitamins and convert food to energy.

These statements are made for a dietary supplement containing calcium glycerophosphate, calcium lactate, carbamide, magnesium citrate, calcium stearate, and calcium acid phosphate. The name of the product is Calsol®.

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.

