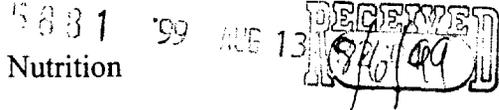




August 3, 1999

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



RE: Ricola® Herbal Health™ Women's Formula

To Whom It May Concern:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Ricola, Inc. ("Ricola"), Morris Plains, New Jersey 07950, hereby notifies the Food and Drug Administration that within the past 30 days the Company has begun marketing a dietary supplement with a label that bears statements of nutritional support. Ricola is the distributor of this product.

The dietary supplement for which the statements are made is Ricola® Herbal Health™ Women's Formula. Per serving size of two tablets, the supplement contains: Tri-source isoflavone concentrate, 125 mg (standardized extract of kudzu root, red clover flower and soy germ); Black cohosh root standardized extract, 80 mg; Women's support herbal blend, 200 mg (standardized extract of licorice root, chaste tree berry and dong quai root); Bio-enhancing herbal blend, 25 mg (extracts of hyssop, lemon balm leaf, peppermint leaf, sage leaf and thyme leaf); Vitamin E, 60 IU; Vitamin B<sub>6</sub>, 20 mg; Calcium, 400 mg; and Magnesium, 200 mg.

The statements of nutritional support for this product read as follows:

- Ricola® Herbal Health™ Women's Formula is scientifically designed for women in every lifestage.
- More than just an excellent source of calcium, magnesium and natural vitamin E, this complete protective formula helps to promote healthy hormonal balance with a unique herbal blend including black cohosh, chaste berry and isoflavones.
- Ricola Herbal Health Women's Formula is further enhanced by a special blend of healthful Ricola herbs.

A copy of the outer package and inner-container label for the product is attached.

Ricola USA, Inc.  
51 Gibraltar Drive  
Morris Plains, NJ 07950  
Phone: 973-984-6811 ■ 800-323-9073  
Fax: 973-984-6814  
E-mail: info@ricolausa.com

973-0162

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Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
August 3, 1999  
Page 2

These statements are accompanied by the required disclaimer indicating that the statements have not been evaluated by FDA and that the product is not intended to diagnose, treat, cure or prevent any disease.

Ricola certifies that it possesses adequate substantiation for these statements of nutritional support; that the substantiation renders them truthful and non-misleading and thus permissible under the DSHEA; and that the information contained in this notice is complete and accurate.

Sincerely,

A handwritten signature in black ink, appearing to read "Dan Thomas", written in a cursive style.

Dan Thomas  
President

Enclosure

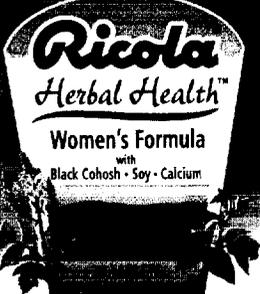
Original plus two copies enclosed

# Ricola® Herbal Health™ Women's Formula

**Directions:** Take two tablets daily, preferably with a meal.

**Caution:** Consult your health professional before using if you are pregnant, nursing a baby, or are taking any prescription medications. Do not purchase if printed neckband seal is broken. This product contains herbal ingredients which may have distinct natural odors.

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62570301



**Ricola Herbal Health™**  
Women's Formula  
with  
Black Cohosh • Soy • Calcium

**Supplement Facts**  
Serving Size: 2 Tablets/Neckband Seal Contains: 15 Tablets

Amount Per Serving	% Daily Value*
Vitamin E (as natural d-alpha-tocopheryl succinate) 200 IU	400%
Vitamin B6 (as pyridoxine hydrochloride) 20 mg	1000%
Calcium (as calcium carbonate) 400 mg	40%
Magnesium (as magnesium oxide) 200 mg	50%

\*Percent Daily Values are based on a diet of other people's dietary supplements.

†Other ingredients: cellulose, cellulose gum, vegetable stearate, silica, vegetable magnesium stearate, and vegetable resin glaze.

9003189 US  
Batch: \_\_\_\_\_  
Exp: \_\_\_\_\_  
Ricola Inc., Morris Plains, NJ 07950  
E.P.O.



**Ricola Herbal Health™**  
Women's Formula  
with  
Black Cohosh • Soy • Calcium

For more than sixty years the world has trusted the Ricola name for herbal products of the highest quality and purity. Today, the tradition continues with Ricola® Herbal Health™ supplements. Meticulously crafted by Swiss experts, these balanced formulas skillfully combine research-recommended levels of highly standardized botanicals with essential vitamins and minerals. Each formula is further enhanced for optimum digestibility with an exclusive blend of helpful Ricola herbs.

Ricola® Herbal Health™ dietary supplements also available:

- Active Memory Formula
- Heart Formula
- Immune Formula
- Prostate Formula
- Antioxidant Formula
- Mood Formula
- Night Time Formula

For comments or questions on Ricola herbal supplements, call 1-800-323-9073, or visit us at [www.ricolausa.com](http://www.ricolausa.com).

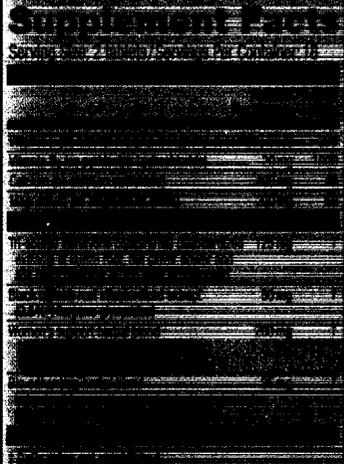
**Directions:** Take two tablets daily, preferably with a meal.

**Caution:** Consult your health professional before using if you are pregnant, nursing a baby, or are taking any prescription medication. Keep out of the reach of children.

Store at 15–30°C (59–86°F) away from heat, light and moisture. Do not purchase if printed neckband seal of bottle is broken. This product contains herbal ingredients, which may have distinct natural odors.

Ricola® Herbal Health™ Women's Formula is scientifically designed for women of every lifestage. More than just an excellent source of calcium, magnesium and natural vitamin E, this complete protective formula helps to promote healthy hormonal balance with a unique herbal blend including black cohosh, chaste berry and isoflavones. Ricola Herbal Health Women's Formula is further enhanced by a special blend of helpful Ricola herbs.

The statements herein have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



Other ingredients: cellulose, cellulose gum, vegetable stearate, silica, vegetable magnesium stearate, and vegetable resin glaze.

Exclusively manufactured for:  
Ricola Inc., Morris Plains, NJ 07950

Exp: \_\_\_\_\_  
Batch: \_\_\_\_\_

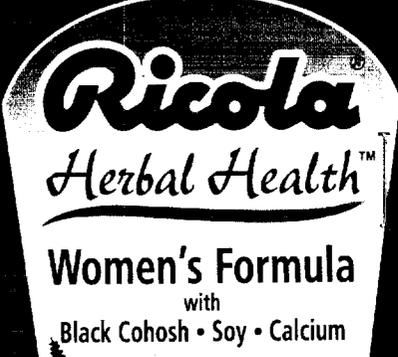


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Trusted  
Herbal Experts  
For 60 Years



**Ricola Herbal Health™**  
Women's Formula  
STANDARDIZED NATURAL  
DIETARY SUPPLEMENT



**Ricola Herbal Health™**  
Women's Formula  
with  
Black Cohosh • Soy • Calcium



DIETARY SUPPLEMENT