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OCT 23 2002

James L. Wilmer, Ph.D.  
Director, Scientific Affairs  
Market America, Inc.  
1302 Pleasant Ridge Road  
Greensboro, North Carolina 27409

Dear Dr. Wilmer:

This is in response to your letter of October 1, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Market America, Inc. is making the following claim, among others, for the product **Feminene™** :

"Feminene™ is a cutting-edge product designed as a natural alternative to traditional treatments that can be taken to help counteract the adverse effects of both PMS and menopause without the possible risk of side effects associated with so many prescription drugs and hormone replacement therapies." - Brochure

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to prevent disease (i.e., it is promoted as an alternative to prescription drugs and hormone replacement therapies that are prescribed for women with premenstrual syndrome or menopause to treat, in part, conditions associated with these states that are diseases, such as severe depression associated with PMS and osteoporosis associated with menopause). This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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You also use the following claims for **Feminene™**: “Vitamin B deficiencies have been associated with a wide range of health challenges, ranging from moodiness to cardiovascular complications. Vitamin B6 and B12 also help reduce homocysteine levels, which has been shown to be a key risk factor for maintaining a healthy heart.” 21 U.S.C. 343(r)(6)(A) provides, among other things, that the labeling of a dietary supplement may bear a statement that “claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States.” The statements you are making for **Feminene™** misbrand this product under 21 U.S.C. 343(r)(6)(A) because they describe a benefit related to a classical nutrient deficiency disease but do not disclose the prevalence of the subject deficiency disease in the United States.

21 U.S.C. 321(g)(1) (last sentence) provides that a food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) (i.e., 21 U.S.C. 321(g)(1)(C)) solely because the label or the labeling contains such a statement. The statements being made for the products **Feminene™** are not made in accordance with 21 U.S.C. 343(r)(6), however, and these statements suggest that the products are intended to treat, prevent, mitigate, or cure diseases or are articles (other than food) intended to affect the structure or any function of the body of man. Therefore, these claims suggest that the product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B) and (C), and that it is subject to regulation under the drug provisions of the Act.

Please contact us if we may be of further assistance.

Sincerely yours,

  
for

John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

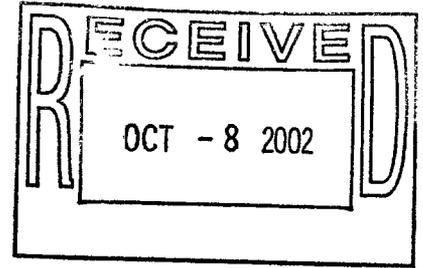
Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Atlanta District Office, Office of Compliance, HFR-SE140

NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND RULE 21 CFR §101.93



This notification is being filed on behalf of **Market America, Inc.** which is the distributor of the product bearing the statements identified in this notification. Its business address is **1302 Pleasant Ridge Road, Greensboro, NC 27409**. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 CFR §101.93. The dietary supplement product on whose label or labeling the statements appear is **Feminene™**.

The text of each structure-function statement for which notification is now being given is:

**Statement 1:** "Feminene™ is a cutting-edge product designed as a natural alternative to traditional treatments that can be taken to help counteract the adverse effects of both PMS and menopause without the possible risk of side effects associated with so many prescription drugs and hormone replacement therapies."—Brochure

**Statement 2:** "Featuring seven different B vitamins, Feminene™ packs a potent blend of these beneficial ingredients into each serving. Vitamin B deficiencies have been associated with a wide range of health challenges, ranging from moodiness to cardiovascular complications. Vitamin B6 and B12 also help reduce homocysteine levels, which has been shown to be a key risk factor for maintaining a healthy heart."—Brochure

The following summary identifies the dietary ingredients or supplements for which a statement has been made:

<u>Statement Number(s)</u>	<u>Identity of Dietary Ingredient or Supplement That Is the Subject of the Statement</u>
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1.-2.	Feminene™ is composed of the following ingredients: vitamin B <sub>1</sub> , vitamin B <sub>2</sub> , vitamin B <sub>3</sub> , vitamin B <sub>5</sub> , vitamin B <sub>6</sub> , folic acid, vitamin B <sub>12</sub> , vitamin E, soy extract, dong quai, evening primrose oil, wild yam, black cohosh, horsetail, red clover, passiflora, valerian root, sage, st. john's wort; other ingredients include: dicalcium phosphate, microcrystalline cellulose, stearic acid, croscarmellose sodium, and silicon dioxide.
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The following identifies the brand name of each supplement for which a statement is made:

82186

**Statement  
Number(s)**

**Brand Name**

**Label or Labeling**

1.-2.

Feminene™

Brochure

I, James L. Wilmer, am authorized to certify this Notification on behalf of Market America, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that Market America, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: October 1, 2002

By: James L. Wilmer

James L. Wilmer, Ph. D.  
Director, Scientific Affairs  
Market America, Inc.