



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JUL 21 2003

Mr. Siddarth Shastri
Vice President, Product Development
Jarrow Formulas
1824 South Robertson Boulevard
Los Angeles, California 90035-4317

Dear Mr. Shastri:

This is in response to your letters of April 18 and May 21, 22, and 28, 2003 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)).

The product **Folic Acid** is using the claim "...adequate folic acid consumption may reduce a woman's risk of having a child with brain or spinal cord defects." The products **Dentashield™** and **Chewable Q-10 + Creatine** are using the claim "Xylitol helps protect dental health by its effects on *Streptococcus mutans*." The product is using the claim "Soy Protein and Heart Disease: Consumption of 25 grams of soy protein...may reduce the risk of heart disease." These statements are not statements of nutritional support subject to 21 U.S.C. 343(r)(6), but health claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized health claims on the relationship between folate and neural tube defects (see 21 CFR 101.79), sugar alcohols and dental caries (21 CFR 101.80), and soy protein and risk of coronary heart disease (21 CFR 101.82). A dietary supplement that meets the eligibility and message requirements set forth in these regulations may bear a claim for the relationship between the respective substance and disease. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in the regulations above would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, making a claim that is not in accordance with the requirements in the respective regulation subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease.

You are also making the claim "mastic has been used for centuries by traditional healers for stomach distress. Mastic Gum protects gastric and duodenal cells and tissue by inhibiting *Helicobacter pylori*" for the product Mastic Gum 500.

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Page 2 - Mr. Siddharth Shastri

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, namely gastric and duodenal ulcers caused by the bacterium *Helicobacter pylori*, which is generally recognized as the bacterium responsible for most ulcers. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

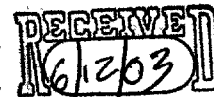
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

1824 South Robertson Blvd.
Los Angeles, CA 90035-4317
310/204-6936 • 800/726-0886
www.Jarrow.com

FAX NUMBERS
Orders 800/890-8955
General 310/204-2520
Administrative 310/204-5132

April 18, 2003

SECTION 403 (r) (6) NOTIFICATION



Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)
5100 Paint Branch Parkway
College Park, Maryland 20740

Dear Sir or Madam:

In accordance with the requirement of Section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act, and Rule CFR 101.93, we are hereby to notify FDA that Jarrow Formulas' **Iso-Rich Soy and Iso-Rich Soy Greens** products bear the following statements:

1. Jarrow Formulas®, Inc., 1824 S. Robertson Blvd., Los Angeles, CA 90035-4317
www.jarrow.com

2. **Statements*:**

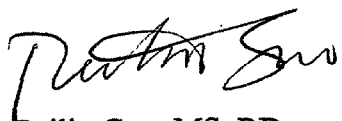
- Soy products may be beneficial for cardiovascular function, menopausal support and bone health.
- Soy isoflavones, along with other naturally occurring soy phytonutrients, have been shown in scientific studies to have many health benefits, including reducing cellular damage, promoting normal cardiovascular function, and enhancing bone health and assisting estrogen balance.
- IP6 supports cellular development and immunity, including enhancing natural killer cell function. IP6 also supports cardiovascular health by binding free iron.
- Saponin, another naturally occurring group of phytonutrients in soy, have been shown in scientific studies to enhance body's defense mechanism.
- Soy Protein and Heart Disease: Consumption of 25 grams of soy protein a day, as a part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease.

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

I certify that the information contained in the notice is complete and accurate, and that Jarrow Formulas has substantiation that the statement is truthful and not misleading.

Sincerely

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Peilin Guo, MS, RD
Dir. Functional Foods & Clinical Research
Jarrow Formulas, Inc.
Ph: 310-204-6936
Fax: 310-736-3174
e-mail: peilin@jarrow.com



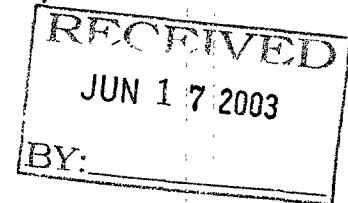
Sid Shastri, CCN
VP-Product Development

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May 22, 2003

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)
5100 Paint Branch Parkway
College Park, Maryland 20740
Reference phone #301-436-2373



Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

(1) Name of Address of distributor:

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

(2) Text of the statement(s):

Co-Q10 (Ubiquinone 10) is an important antioxidant found in every cell of the body and is especially concentrated in heart tissue. It functions in the electron transport chain for the production of cellular energy. Creatine is synthesized in the liver and stored in muscles, including the heart. Creatine is converted to creatine phosphate which donates energy for the synthesis of ATP - the universal currency of energy. The heart requires ATP for muscular contractions, necessary for pumping blood throughout the cardiovascular system.

The taste of Chewable Q-60 + Creatine is enhanced by Xylitol and Lo Han Kuo extract. Both are natural sweeteners providing a pleasant taste and are very low in calories. Xylitol helps promote dental health by inhibiting *Streptococcus mutans*, Lo Han Kuo is a new, exceptionally low-calorie, natural plant sweetener from China's pristine southern mountain area. Sugar free. No fructose.

(3) Name of the dietary ingredient(s) if not provided in the text of the statement:

Coenzyme Q-10 (USP Grade) • Creatine

(4) Name of the dietary supplement(s)

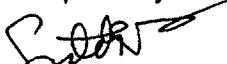
Chewable Q-60 + Creatine 60 mg 60 tablets

(5) The following disclaimer appears on the label in bold:

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

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients.

Respectfully submitted,


Siddharth Shastri
Vice President, Product Development

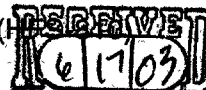
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May 22, 2003

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Office of Nutritional Products, Labeling, and Dietary Supplements
5100 Paint Branch Parkway
College Park, Maryland 20740
Reference phone #301-436-2373



Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

(1) Name of Address of distributor:

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

(2) Text of the statement(s):

DentaShield is nutrition for healthy teeth and gum function and oral antioxidant status, combining CoQ10, Lactoferrin, Metabolin, Cranberries, Green Tea, Xylitol and Calcium. Coenzyme Q10 (CoQ10) is a potent antioxidant critically involved in the mitochondrial production of energy.

Lactoferrin is a glycoprotein found in whey. Freeze dried lactoferrin ensures the immune promoting activities of this protein. Metabolin contains the beneficial metabolites and cell walls of lactic and propionic acid producing bacteria. These beneficial bacterial compounds help support oral immune defense.

Cranberries contains the vital acids quinic, benzoic and hippuric, and the potent antioxidant proanthocyanidins (OPCs). Green Tea Extract promotes circulation and contains potent free radical scavenging flavonoids known as catechins. Xylitol helps protect dental health by its effects on *Streptococcus mutans*.

(3) Name of the dietary ingredient(s) if not provided in the text of the statement:

Calcium (as Citrate) • Coenzyme Q10 • Lactoferrin (freeze dried) • Green Tea 5:1 Extract (*Camellia sinensis*)(45% polyphenols) • Metabolin • Cranberry (*Vaccinium macrocarpon*) • Gamma Tocopherol • Xylitol

(4) Name of the dietary supplement(s)

Dentashield™ 60 chewable tablets

(5) The following disclaimer appears on the label in bold:

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

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients.

Respectfully submitted,


Siddharth Shastri
Vice President, Product Development

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5100 Paint Branch Parkway
College Park, Maryland 20740
Reference phone #301-436-2373

May 28, 2003
JUN 17 2003

Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

(1) Name of Address of distributor:

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

(2) Text of the statement(s):

Folic Acid is a B vitamin and a crucial nutrient for the health of the heart and normal fetus development. Folic acid is a methyl donor needed to reduce homocysteine back to methionine and for accurate synthesis of DNA and normal cell division throughout life including during pregnancy.

Scientific research demonstrates that adequate folic acid consumption may reduce a woman's risk of having a child with brain or spinal cord defects.

(3) Name of the dietary ingredient(s) if not provided in the text of the statement:

Folic Acid

(4) Name of the dietary supplement(s)

Folic Acid 800 mcg • 100 capsules

(5) The following disclaimer appears on the label in bold:

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

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients.

Respectfully submitted,


Siddharth Shastri, CCN
Vice President, Product Development

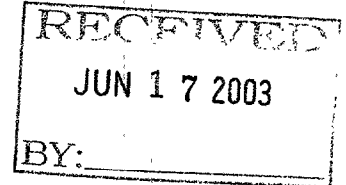
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May 22, 2003

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)
5100 Paint Branch Parkway
College Park, Maryland 20740
Reference phone #301-436-2373



Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

(1) Name of Address of distributor:

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

(2) Text of the statement(s):

Mastic Gum 500 contains natural tree stem mastic gum (*Pistacia lentiscus*) from a shrub-like tree grown mainly in Greece and Turkey. Mostly composed of resinous gum and volatile oils, mastic has been used for centuries by traditional healers for stomach distress. Mastic Gum protects gastric and duodenal cells and tissue by inhibiting *Helicobacter pylori*.

(3) Name of the dietary ingredient(s) if not provided in the text of the statement:

Mastic Gum (*Pistacia lentiscus*)

(4) Name of the dietary supplement(s)

Mastic Gum 500 500 mg 60 tablets

(5) The following disclaimer appears on the label in bold:

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

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients.

Respectfully submitted,

Siddharth Shastri
Vice President, Product Development

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