



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

0205 '00 DEC -7 P3:08

Siddharth Shastri
Director of Product Development
Jarrow Formulas, Inc.
1824 South Robertson Blvd.
Los Angeles, CA 90035-4317

DEC 4 2000

Dear Mr. Shastri:

This is in response to your letter to the Food and Drug Administration (FDA), dated August 14, 2000, 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 Jarrow Formulas, Inc. is making the following claims, among others, for the product "**Ultra Bone Up (120 Tablets):**"

"In conjunction with regular, weight-bearing exercise and healthy diet with adequate calcium, including from Ultra Bone-Up, helps teen and young adult women build bone mass and maintain bone health and may reduce their high risk of osteoporosis later in life."

In so far as this statement is based on the relationship solely between the calcium in the product and osteoporosis it is not a claim subject to 21 U.S.C. 343(r)(6), but is a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. 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 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343 (r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 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 osteoporosis

However, if the claimed relationship between the product and osteoporosis is based on the presence of the other dietary ingredients, as well as the calcium, then the claim suggests that this product is intended to treat, cure, prevent, or mitigate a disease. 21 U.S.C. 343(r)(6) makes clear that a statement included in the labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. 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

995-0163

LET 431

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.

Please contact us if we may be of further assistance.

Sincerely,

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, Los Angeles District Office, Compliance Branch, HFR-PA240

Cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-811 (r/f, file)
HFD-40 (Behrman)
HFD-310
HFD-410 (Aronson)
HFS-605
HFV-223 (Benz)
GCF-1 (Nickerson, Dorsey)
Ft/ljm:HFS-811:111500: 72128 ultra bone up.

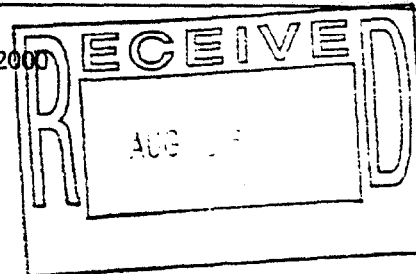
JARROW FORMULAS, INC.
SUPERIOR NUTRITION
AND FORMULATION

1824 South Robertson Boulevard
Los Angeles, CA 90035-4317
(310) 204-6936
Toll Free (800) 726-0886
FAX (310) 204-2520

JARROW
FORMULAS™

Division of Compliance and Enforcement/ONPLDS
Center for Food Safety and Applied Nutrition
Food and Drug Administration
HFS-810
200 C Street, S.W.
Washington, DC 20204
202-205-5229

August 14, 2000



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):**

"Promotes Bone Density" – Ultra Bone-Up combines Ipriflavone (a flavonoid that reduces calcium loss from bone and promotes bone density), Glucosamine and MSM (to support the synthesis of glycosaminoglycans that compose the organic matrix of bone tissue) with Microcrystalline Hydroxyapatite (MCHA) calcium, from free range Australian calves
Health Claim: In conjunction with regular, weight-bearing exercise and a healthy diet with adequate calcium, including from Ultra Bone-Up, helps teen and young adult women build bone mass and maintain bone health and may reduce their high risk of osteoporosis later in life. Daily calcium intake above 2,000 mg is not likely to provide additional benefit
Adequate calcium intake is linked to slowing bone loss in older men and women

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

Combination of microcrystalline hydroxyapatite, glucosamine hydroxyapatite, ipriflavone, MSM, vitamin C, vitamin D3, vitamin K1, magnesium, zinc, copper, manganese and boron.

(4) **Name of the dietary supplement(s)**

Ultra Bone Up (120 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. A compendium of relative published research substantiating the above statement(s) is on file at the corporate office.

Respectfully submitted,

Siddharth Shastri, CCN

Vice President, Director of Product Development
Licensed Dietitian/Clinical Nutritionist, #002378
(by the University of the State of New York, State Board of Education)

72128

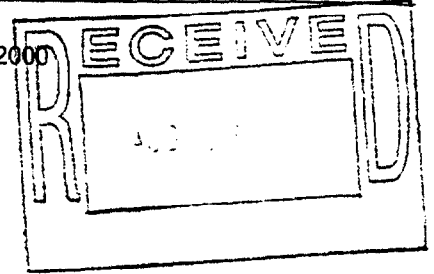
JARROW FORMULAS, INC.
SUPERIOR NUTRITION
AND FORMULATION

1824 South Robertson Boulevard
Los Angeles, CA 90035-4317
(310) 204-6936
Toll Free (800) 726-0886
FAX (310) 204-2520

JARROW
FORMULAS™

Division of Compliance and Enforcement/ONPLDS
Center for Food Safety and Applied Nutrition
Food and Drug Administration
HFS-810
200 C Street, S.W.
Washington, DC 20204
202-205-5229

August 14, 2000



Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 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):

"Promotes Bone Density" – Ultra Bone-Up combines Ipriflavone (a flavonoid that reduces calcium loss from bone and promotes bone density), Glucosamine and MSM (to support the synthesis of glycosaminoglycans that compose the organic matrix of bone tissue) with Microcrystalline Hydroxyapatite (MCHA) calcium, from free range Australian calves.
Health Claim: In conjunction with regular, weight-bearing exercise and a healthy diet with adequate calcium, including from Ultra Bone-Up, helps teen and young adult women build bone mass and maintain bone health and may reduce their high risk of osteoporosis later in life. Daily calcium intake above 2,000 mg is not likely to provide additional benefit. Adequate calcium intake is linked to slowing bone loss in older men and women.

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

Combination of microcrystalline hydroxyapatite, glucosamine hydroxyapatite, ipriflavone, MSM, vitamin C, vitamin D3, vitamin K1, magnesium, zinc, copper, manganese and boron.

(4) Name of the dietary supplement(s)

Ultra Bone Up (120 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. A compendium of relative published research substantiating the above statement(s) is on file at the corporate office.

Respectfully submitted,

Siddharth Shastri, CCN

Vice President, Director of Product Development
Licensed Dietitian/Clinical Nutritionist, #002378
(by the University of the State of New York, State Board of Education)

7/21/20