



2102 '03 APR 18 P1:59

APR - 7 2003

Arun Chainani, M.D.
AuMed, Inc.
P. O. Box 245
Valley Cottage, New York 10920

Dear Dr. Chainani:

This is in response to your submission to the Food and Drug Administration (FDA), received by FDA on October 28, 2002. Your submission is intended to be the notification required by 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a).

21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submission does not meet this requirement in that the notice does not contain the signature of a responsible individual nor does it certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit notifications in accordance with the requirements in 21 CFR 101.93(a).

Nonetheless, in resubmitting your notification, you should be aware that the labeling of four of the products that are the subject of your submission bear claims that do not appear to be claims subject to 21 U.S.C. 343(r)(6). You submitted reference booklets that you distribute in conjunction with the marketing of the products **Youthmed**, **Glucomed**, **Hartmed**, and **Ostemed**. Each booklet contains numerous references to the use of these products and/or their ingredients in the treatment, prevention, cure, or mitigation of diseases.

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 statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not

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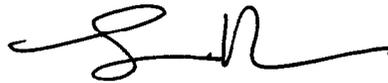
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meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you 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 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

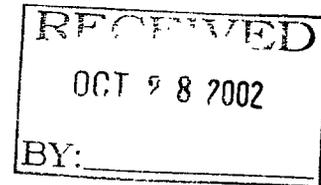
Copies:

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, New York District Office, Office of Compliance, HFR-NE140



The Gold Standard in Health Care

Dr. Elizabeth Yetley
Office of Special Nutritionals (HFS-450)
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204



Re: Fulfillment of Reporting Obligation Under 21 U.S.C.# 343(r) and 21 CFR # 101.93

Dear Dr. Yetley:

AuMed Inc, in accordance with 21 U.S.C. # 343(r) and 21 CFR # 101.93, hereby submits an original and two copies of its notification with the statements presented below. Please note, these statements/references noted in the Scientific References are aimed at health care professionals as part of an integrated care marketing promotion; these statements are not included on any labels (all labels enclosed) but included in the sub-set of brochures for health care professionals (as part of nutritional support for conventional standards of care). AuMed Inc retains scientific documentation/texts supporting the statements and makes its Scientific References available to health care professionals. (Representative scientific references for health care professionals enclosed with this letter).

In accordance with 21 USC # 343(r)(6) and 21 CFR # 101.93(c), each of the statements of nutritional support are cross-referenced on the very same page next to which the following statement will appear "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." In addition, AuMed also notes that all AuMed products are recommended in conjunction with a healthy lifestyle that includes a balanced diet and exercise.

Also note, AuMed nutritional supplements are only made available via health care professionals as part of an integrated health care approach (as part of nutritional support for conventional standards of care).

Respectfully submitted,

Arun Chainani, M.D.

AuMed Toll Free Tel: (877) AuMed Inc = (877) 286-3346
AuMed Mailing Address: AuMed Inc, P.O. Box 245, Valley Cottage, NY 10920

AuMed Inc.



The Gold Standard in Health Care

PRODUCT/BRAND DESCRIPTIONS:

COREMED:

COREMED is a multivitamin that is designed to provide balanced vitamin and mineral profiles. It can help optimize healthy lifestyles and may provide broad-spectrum anti-oxidant protection with its optimal dose and ratio of nutrients and its superior chelated mineral salt forms. COREMED multivitamin is an effective adjuvant that complements other AuMed professional brands.

HARTMED:

HARTMED is a health supplement aimed at providing cardiovascular care. This comprehensive scientific formulation provides credible natural vegetarian ingredients and standardized extracts in small easy to swallow vegetarian capsules. COREMED multivitamin also complements HARTMED as an effective adjuvant.

OSTEMED:

OSTEMED is a health supplement formulated for joint care. This comprehensive scientific formulation provides credible natural ingredients and standardized extracts in small easy to swallow capsules. COREMED multivitamin (and adequate calcium intake) also complements OSTEMED as an effective adjuvant.

GLUCOMED:

GLUCOMED is a health supplement aimed at optimal glucose and weight balance. This comprehensive scientific formulation provides credible natural vegetarian ingredients and standardized extracts in small easy to swallow vegetarian capsules. COREMED multivitamin also complements GLUCOMED as an effective adjuvant.

YOUTHMED:

YOUTHMED is a health supplement aimed at supporting a healthy aging process –youthful skin, vision, and memory- so that you may look young, feel young, and stay young. This comprehensive scientific formulation provides credible natural vegetarian ingredients and standardized extracts in small easy to swallow vegetarian capsules. COREMED multivitamin also complements YOUTHMED as an effective adjuvant.

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AuMed Inc., New York, NY, USA
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REPLENISHING LIFE

Dietary Supplement
120 Hypoallergenic Vegetarian Capsules

The Standard In Health Care

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Supplement Facts

Serving Size: 1 Capsule

Amount per capsule	%Daily Value	Amount per capsule (cont.)	%Daily Value
Vitamin A	1250 IU 25	Selenium	15 mcg 21
(200 IU as acetate & 950 IU as beta carotene)		(as selenite methionine)	
Vitamin C (as ascorbic acid)	100 mg 166	Copper (as gluconate)	0.5 mg 25
Vitamin D (as cholecalciferol)	50 IU 12	Manganese (as gluconate)	1.5 mg 25
Vitamin E	50 IU 166	Chromium (as picolinate)	1.5 mcg 20
(as d-alpha-tocopheryl succinate)		Molybdenum (A.A. chelate)	15 mcg 20
Vitamin B1 (as thiamine mononitrate)	10 mg 666	Vitamins B6, B12, B1, B2, B3, B5, B7, B9, B10, B11, B12, B13, B14, B15, B16, B17, B18, B19, B20, B21, B22, B23, B24, B25, B26, B27, B28, B29, B30, B31, B32, B33, B34, B35, B36, B37, B38, B39, B40, B41, B42, B43, B44, B45, B46, B47, B48, B49, B50, B51, B52, B53, B54, B55, B56, B57, B58, B59, B60, B61, B62, B63, B64, B65, B66, B67, B68, B69, B70, B71, B72, B73, B74, B75, B76, B77, B78, B79, B80, B81, B82, B83, B84, B85, B86, B87, B88, B89, B90, B91, B92, B93, B94, B95, B96, B97, B98, B99, B100, B101, B102, B103, B104, B105, B106, B107, B108, B109, B110, B111, B112, B113, B114, B115, B116, B117, B118, B119, B120	
Vitamin B2 (as riboflavin)	10 mg 500	Calcium (as calcium carbonate)	10 mg 2
Niacin	10 mg 50	(as d-calcium pantothenate)	
(5 mg as succinylated and 5 mg as immediate release)		Vitamin B5 (as pantoic acid HCl)	10 mg 20
Vitamin B6 (as pyridoxine HCl)	10 mg 20	Vitamin B12 (as cyanocobalamin)	15 mcg 250
Vitamin B12 (as cyanocobalamin)	15 mcg 250	Iron (as ferrous fumarate)	15 mg 5
Iron (as ferrous fumarate)	15 mg 5	Pantoic Acid	15 mg 150
Pantoic Acid	15 mg 150	(as d-calcium pantothenate)	
(as d-calcium pantothenate)		Calcium (as calcium carbonate)	10 mg 2
Calcium (as calcium carbonate)	10 mg 2	Magnesium (as citrate)	15 mg 4
Magnesium (as citrate)	15 mg 4	Zinc (as zinc gluconate)	1.5 mg 15
Zinc (as zinc gluconate)	1.5 mg 15		

* Daily values not established.

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For information contact AuMed, USA

Directions: Take 1 to 2 capsules twice daily, or as directed by your physician.

Caution: Use only under the supervision of your physician. Keep this product and other capsules and pills in a cool, dry place at a temperature of 59-86°F (15-30°C) and out of the reach of children. Do not use if the cap or outer seal is broken.

AuMed use recommendations formulated in conjunction with a healthy lifestyle that includes a balanced diet and exercise.

AuMed Inc., New York, NY, USA
Toll Free Tel: (877) AuMed Inc (877) 286-3346



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The Gold Standard in Health Care

YouthMed
YOUR FOUNTAIN OF YOUTH

Dietary Supplement
120 Hypoallergenic Vegetarian Capsules

The Standard In Health Care

www. Med.com

Supplement Facts

Serving Size: 1 Capsule

Amount per capsule	%Daily Value
Vitamin A (as mixed carotenoids)	500 IU 10
Vitamin E (as mixed tocopherols)	25 IU 83
Acetyl L-Carnitine	25 mg *
N-Acetyl Cysteine (N.A.C.)	20 mg *
Grape Seed (Vitis vinifera seed Ext. 95%)	10 mg *
Bilberry (Vaccinium myrtillus fruit Ext. 25%)	10 mg *
Ginkgo Biloba (Ginkgo biloba leaf Ext. 24%)	10 mg *
Beta D-Glucan	2 mg *
Lutein	1 mg *
Vinpocetine	1 mg *

* Daily value not established.

Other Ingredients: Oval Root Plant, Black, Magnesium Stearate, Water, Hydroxypropyl Methylcellulose.
No Added Sugar, Starch, Yeast, Corn, Artificial Colors or Flavors.

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OSTEMED

TOTAL JOINT CARE FORMULA

Dietary Supplement
120 Hypoallergenic Capsules

Supplement Facts

Serving Size: 1 Capsule

Amount per capsule:	%Daily Value
Vitamin D (as cholecalciferol)	50 IU 12
Glucosamine Sulfate (as potassium salt)	150 mg
Chondroitin Sulfate	100 mg
Methyl Sulfonyl Methane (MSM)	75 mg
Turmeric (Curcuma longa root Ext. 95%)	50 mg
Boswellia acid (Boswellia serrata gum resins)	25 mg
Bromelain (2400 GDU)	15 mg
White Willow (Salix alba herb)	15 mg
Devil's Claw (Harpagophytum procumbens root) (8% Harpagosides)	12.5 mg
Horsetail (Equisetum arvense herb) 18% silica	7.5 mg
Quercetin	7.5 mg
Boron (as citrate, aspartate, glycinate)	1 mg
Undenatured Type II Collagen	150 mcg

* Daily value not established.

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HEARTMED

COMPLETE
CARDIOVASCULAR CARE

Dietary Supplement
120 Hypoallergenic Vegetarian Capsules

Supplement Facts

Serving Size: 1 Capsule

Amount per capsule:	%Daily Value
Niacin (as inositol hexanicotinate)	50 mg 250
Folic Acid	75 mcg 18
Vitamin B12 (as cyanocobalamin)	15 mcg 250
Magnesium (as citrate)	30 mg 7
Selenium (as glycinate, methionate)	15 mcg 21
Potassium (as aspartate)	5 mg <1
Guggul (Commiphora mukul herb 2.5%)	75 mg
Garlic (Allium sativum root)	75 mg
L-Taurine	50 mg
Arjun (Terminalia arjuna bark)	50 mg
Dan Shen (Salvia miltiorrhiza root)	40 mg
Hawthorne	40 mg
(Crataegus oxyacantha berries Ext.) (2.2% Vitexin)	
L-Carnitine (HCl)	10 mg
Alpha Lipoic Acid	10 mg
Gamma-oryzanol	7.5 mg
CoEnzyme Q-10	5 mg

* Daily value not established.

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Formulation: Glucomed 120 USA

Directions: Take 1 to 2 capsules twice daily, or as directed by your physician.

Caution: Use only under the supervision of your physician. Keep tightly closed, and store in a cool dry place at a temperature of 30°-60° F (10°-30° C), and out of the reach of children. Do not use if you are under medical supervision.

AuMed and its associated products are in conjunction with a healthy lifestyle that includes a balanced diet and exercise.

AuMed Inc, New York, NY, USA
Toll Free Tel: (877) AuMed Inc (877) 286-3346



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The Gold Standard in Health Care

GLUCOMED

OPTIMAL GLUCOSE BALANCE

Dietary Supplement
120 Hypoallergenic Vegetarian Capsules

Supplement Facts

Serving Size: 1 Capsule

Amount per capsule:	%Daily Value
Niacin (as niacinamide)	50 mg 250
Vitamin B12 (as cyanocobalamin)	15 mcg 250
Chromium (as picolinate)	75 mcg 62
Inositol	50 mg
L-Arginine	50 mg
Bitter Melon (Momordica charantia fruit Ext.)	50 mg
Gymnema (Gymnema sirtene leaf Ext. 4:1) (25% Gymnemic acid)	50 mg
Globe Artichoke (Cynara scolymus leaf Ext. 2.5%)	30 mg
Milk Thistle (Silybum marianum herb Ext. 80%)	15 mg
Goldenrod (Solidago herb)	15 mg
Jambol (Syzygium Jambolanum leaf)	15 mg
Fenugreek (Trigonella foenum-graecum seed Ext. 50%)	15 mg
Prickly Pear (Opuntia spp. herb)	15 mg
Vanadyl Sulfate	15 mg
Alpha Lipoic Acid	10 mg
Bilberry (Vaccinium myrtillus fruit) (20% anthocyanadins)	5 mg
Ginkgo (Ginkgo biloba leaf Ext. 24%)	5 mg
Devil's Claw (Oplopanax horridus leaf Ext. 4:1)	5 mg
Goat's Rue (Galago officinalis herb Ext. 4:1)	5 mg
Baraba (Lagerströmia speciosa leaf Ext.) (1% Corsolic acid)	5 mg

* Daily value not established.

Other Ingredients: Cellulose, Hydroxypropyl Methylcellulose, Croscarmellose, Stearic Acid, Magnesium Stearate, Polyethylene Glycol, Talc, and Colloidal Silicon Dioxide.

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