



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT 23 2000

9 6 9 7 '00 OCT 25 P 2:22

Mr. Miles Mitchell
General Manager
Aura Shop, Inc.
520 Washington, Boulevard
PMB 907
Marina Del Rey, California 90292

Dear Mr. Mitchell:

This is in response to your letter to the Food and Drug Administration (FDA), dated September 27, 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 the Aura Shop, Inc. is making the following claims, among others, for the following products:

Harmony

“...strengthening resistance against colds, flu and other systemic infections”

Happiness

“...treatment for anxiety, anorexia and depression”

Inner Peace

...lowering blood pressure...”

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, including the name of the product AllerPro,” suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not 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.

978-0163

LET408

Page 2 - Mr. Miles Mitchell

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 (BWilliams)
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz)
GCF-1 (Nickerson, Dorsey)
f/t:rjm:HFS-811:10/13/00:72830.adv:disc51

see
docket
975-0163

This statement has not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



ALL NATURAL DIETARY FOOD SUPPLEMENT FORMULATED
TO INCREASE YOUR AURA POWER

HARMONY

Echinacea, Goldenseal and Zinc are known by scientists to have a positive effect on our immune system, increasing inner balance and harmony while strengthening resistance against colds, flu and other systemic infections. Especially recommended for GREEN and RED aura types.

www.aurashop.com

60 Capsules • High Quality Pharmaceutical Grade

Serving Size: 1 Capsule
Servings Per Container: 60

Supplement Facts

Each Serving Contains:	% DV
ZINC (as Zinc Oxide)	10.00 mg 66.67
ECHINACEA HERB	250.00 mg *
GOLDEN SEAL HERB	250.00 mg *

*Daily Value (DV) not established.

Other Ingredients: Gelatin, Rice Powder, Talc, Hydroxypropyl Cellulose & Silicon Dioxide.

Suggested Use: As a dietary supplement, take one (1) capsule daily.

Warning: Pregnant or nursing women should consult their physician before using this product. Keep out of the reach of children.

Store at room temperature, tightly closed. Avoid excessive heat.

Important: Tamper evident seal under cap. Do not use if seal is broken or missing.

This statement has not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



ALL NATURAL DIETARY FOOD SUPPLEMENT FORMULATED
TO INCREASE YOUR AURA POWER

CREATIVITY

This combination of herbs has been known to increase colon activity and eliminate toxins in your body. The result will be increased physical energy resulting in a more productive life style. A clean colon and intestine are essential for a vital, healthy and creative life style. Especially recommended for ORANGE and BLUE aura types.*

www.aurashop.com

60 Capsules • High Quality Pharmaceutical Grade

Serving Size: 1 Capsule
Servings Per Container: 60

Supplement Facts

Each Serving Contains:	
CASCARA SAGRADA BARK**	65.00 mg * RHUBARB ROOT 45.00 mg *
BARBERRY BARK	60.00 mg * YARROW HERB***
FENNEL SEED	65.00 mg * CAYENNE FRUIT 5.00 mg *
GINGER ROOT	60.00 mg * RASPBERRY LEAF 5.00 mg *
LICORICE ROOT	60.00 mg * GOLDEN SEAL HERB 5.00 mg *
RAU D'ARCO BARK	47.00 mg * PEPPERMINT LEAF 800.00 mcg *

*Daily Value (DV) not established.

Other Ingredients: Gelatin, Magnesium Silicate, Hydroxypropyl Cellulose and Silicon Dioxide.

Suggested Use: As a dietary supplement, take one (1) capsule daily.

Warning: Pregnant or nursing women should consult their physician before using this product. Keep out of the reach of children. Store at room temperature, tightly closed. Avoid excessive heat.

Important: Tamper evident seal under cap. Do not use if seal is broken or missing.

** Do not use this product if you have abdominal pain or diarrhea. Consult a health-care provider prior to use if you are pregnant or nursing a baby. Discontinue use in the event of diarrhea or watery stools. Do not exceed recommended doses. Not for long term use.

*** May be harmful if used incorrectly. Proper usage information should be obtained by consulting a health professional or proper reference materials before using.

see
docket
975-0163

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ALL NATURAL DIETARY FOOD SUPPLEMENT FORMULATED
TO INCREASE YOUR AURA POWER

HAPPINESS

This formula has been commonly used as a treatment for anxiety, anorexia and depression. It also has been known to increase mental focus while creating a sense of happiness and lightness. Use this powerful herb to help relieve stress naturally and to experience emotional balance. Especially recommended for ORANGE and VIOLET aura types.*

www.aurashop.com

60 Capsules • High Quality Pharmaceutical Grade

Supplement Facts

Serving Size: 1 Capsule
Servings Per Container: 60

Each Serving Contains:	% DV
ST. JOHN'S WORT HERB EXTRACT	300.00mg *

*Daily Value (DV) not established.

Other Ingredients: Gelatin, Microcrystalline Cellulose, Stearic Acid, Talc & Silicon Dioxide.

Suggested Use: As a dietary supplement, take one (1) capsule daily.

Warning: Pregnant or nursing women should consult their physician before using this product. Keep out of the reach of children.

Store at room temperature, tightly closed. Avoid excessive heat.

Important: Tamper evident seal under cap. Do not use if seal is broken or missing.

see
docket
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ALL NATURAL DIETARY FOOD SUPPLEMENT FORMULATED TO INCREASE YOUR AURA POWER

INNER PEACE

Enzymes are essential in digesting and absorbing vitamins and nutrients. Now you can replace those important enzymes that are lost during the aging process. This formula acts as an anti-oxidant and has been known to improve the immune system, cardiovascular system while lowering blood pressure and increasing sensitivity, creativity and emotional balance. Especially recommended for **INDIGO-BLUE** and **ORANGE** aura types.

www.aurashop.com

60 Capsules • High Quality Pharmaceutical Grade

Supplement Facts	
Serving Size: 1 Capsule Servings Per Container: 60	
Each Serving Contains:	% DV
COENZYME Q10	25.00 mg *
*Daily Value (DV) not established.	

Other Ingredients: Rice Powder, Gelatin, Silicon Dioxide and Stearic Acid.
Suggested Use: As a dietary supplement, take one (1) capsule daily.
Warning: Pregnant or nursing women should consult their physician before using this product. Keep out of the reach of children. Store at room temperature, tightly closed. Avoid excessive heat. Important: Tamper evident seal under cap. Do not use if seal is broken or missing.

This statement has not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



ALL NATURAL DIETARY FOOD SUPPLEMENT FORMULATED TO INCREASE YOUR AURA POWER

HIGH VIBRATIONS I FRUITS

A special blend of fresh raw fruits in a revolutionary new concentrated form. There is no easier and better way to get your daily portion of fruits. This Hi-Vibration Fruit Formula is known to give you quality nutrients to raise your energy to a higher level. Especially used in conjunction with meditative and healing activities. This formula is recommended for **ALL** Aura Color Types.

www.aurashop.com

60 Capsules • High Quality Pharmaceutical Grade

Supplement Facts		
Serving Size: 1 Capsule Servings Per Container: 60		
Each Serving Contains:		
APPLE FIBER 40.00mg *	PEACH FRUIT 30.00mg *	LPASE 20.00mg *
GRAPE SEED EXTRACT 35.00mg *	PRUNE FRUIT 30.00mg *	BROMELAIN 20.00mg *
ORANGE FRUIT 35.00mg *	CRANBERRY 30.00mg *	PAPAIN 20.00mg *
PAPAYA FRUIT 35.00mg *	LEMON FRUIT 25.00mg *	CELLULASE 20.00mg *
PINEAPPLE FRUIT 35.00mg *	CITRUS PECTIN 25.00mg *	ACIDOPHILLUS 15.00mg *
*Daily Value (DV) not established.		

Other Ingredients: Gelatin, Calcium Phosphate Dibasic, Magnesium Silicate, Hydroxypropyl Cellulose and Silicon Dioxide.
Suggested Use: As a dietary supplement, take one (1) capsule daily.
Warning: Pregnant or nursing women should consult their physician before using this product. Keep out of the reach of children. Store at room temperature, tightly closed. Avoid excessive heat. Important: Tamper evident seal under cap. Do not use if seal is broken or missing.

This statement has not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



ALL NATURAL DIETARY FOOD SUPPLEMENT FORMULATED TO INCREASE YOUR AURA POWER

HIGH VIBRATIONS II VEGETABLES

A special blend of fresh raw vegetables in a revolutionary new concentrated form. There is no easier and better way to get your daily portion of vegetables. This Hi-Vibration Vegetable Formula is known to give you quality nutrients to raise your energy to a higher level. Especially used in conjunction with meditative and healing activities. This formula is recommended for **ALL** Aura Color Types.

www.aurashop.com

60 Capsules • High Quality Pharmaceutical Grade

Supplement Facts		
Serving Size: 1 Capsule Servings Per Container: 60		
Each Serving Contains:		
OAT BRAN FLOUR 30.00 mg *	PARSLEY LEAF 22.00 mg *	LPASE 14.00 mg *
BROCCOLI FLOWERS 28.00 mg *	GRINGO LEAF 21.00 mg *	CELLULASE 13.00 mg *
CABBAGE LEAF 28.00 mg *	(Kibigo Brocol) *	BROMELAIN 12.00 mg *
WHEAT GRASS 27.00 mg *	MILK THISTLE SEED 20.00 mg *	PAPAIN 11.00 mg *
BARLEY GRASS 25.00 mg *	CAULIFLOWER 18.00 mg *	AMYLASE 10.00 mg *
SPINACH LEAF 25.00 mg *	GARLIC ROOT 18.00 mg *	BETATENE 8.00 mg *
BET ROOT 24.00 mg *	CARROT ROOT 17.00 mg *	CHLOROPHYLL 8.00 mg *
ASPARAGUS (WHOLE) 23.00 mg *	OLUCOMANNAN ROOT 18.00 mg *	CAMELLIA SINENSIS EXTRACT (Green Tea) 2.00 mg *
	ACIDOPHILLUS 18.00 mg *	
*Daily Value (DV) not established.		

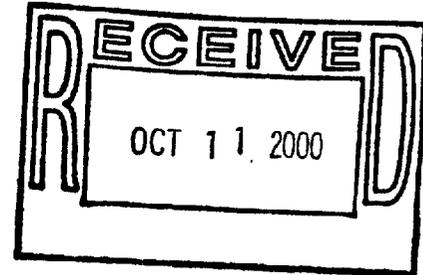
Other Ingredients: Gelatin, Magnesium Silicate, Hydroxypropyl Cellulose & Silicon Dioxide.
Suggested Use: As a dietary supplement, take one (1) capsule daily.
Warning: Pregnant or nursing women should consult their physician before using this product. Keep out of the reach of children. Store at room temperature, tightly closed. Avoid excessive heat. Important: Tamper evident seal under cap. Do not use if seal is broken or missing.



72830

September 27, 2000

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington DC 20204



To Whom It May Concern:

Aura Shop Inc. will distribute nine dietary supplements that will include the enclosed labels. All statements and ingredients are provided on enclosed copies of supplement labels. These products will be privately labeled by our company and will be manufactured for us by Paragon Laboratories of Torrance, California. Aura Shop Inc. is located at the following address: 520 Washington Blvd. PMB # 907 Marina del Rey, California 90292.

All statements and information contained in this notice are complete and accurate. Our firm keeps, in our records, substantiation that these statements are truthful and are not misleading.

Regards,

A handwritten signature in black ink, appearing to read "Miles Mitchell".

Miles Mitchell
General Manager
Aura Shop Inc.
310-390-7090 ext. 208
miles@aura.net