



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

docket

Food and Drug Administration
Washington, DC 20204

AUG 25 1998

7896 01 JUN 11 P2:04

President
21st Century Laboratories, Inc.
2445 W. 12th Street
Unit 2
Tempe, Arizona 85281

Dear Sir:

This is in response to your letter of August 4, 1998 to the Food and Drug Administration (FDA) concerning statements being made for dietary supplements marketed by 21st Century Laboratories, Inc.

Your letter appears to be the submission required pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). However, your submission does not conform to the requirements in Title 21 of the Code of Federal Regulations (21 CFR) 101.93, specifically, the requirement in 21 CFR 101.93(a)(3) that the "notice shall be signed by a responsible individual or the person who can certify the accuracy of the information presented and contained in the notice," because the submission is unsigned.

Therefore, the agency will take no further action on this submission and this letter is to advise you that you have not complied with the requirements of 21 U.S.C. 343(r)(6) of the Act. If you intend to make claims for your products under 21 U.S.C. 343(r)(6), you must submit the notification (and 2 copies; 21 CFR 101.93(a)(1)) required by that section within 30 days after first marketing of a dietary supplement that bears one of the statements listed in 21 U.S.C. 343(r)(6).

Please contact us if we may be of further assistance.

Sincerely,

Robert J. Moore, Ph.D.
Senior Regulatory Scientist
Division of Programs and Enforcement Policy
Office of Special Nutritionals

cc:
HFA-224 (w/incoming)
HFS-22 (CCO)
HFS-456 (file)
HFS-450 (r/f, file)
f/t:HFS-456:rjm:8/25/98:docname:century.adv:disc31

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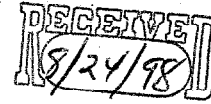
21ST Century Laboratories, Inc.

2445 W. 12th Street, Unit 2, Tempe, Arizona 85281 U.S.A. • phone (602) 966-8201 • fax (602) 966-5395



4 August 1998

Office of Special Nutritionals (HFS-450)
FDA-CFSAN
200 C Street, S.W.
Washington, DC 20204



Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula to Fortify the Body's Support Systems Especially During the Winter Season.

Dietary ingredient to which the statement refers: Elderberry Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Elderberry Extract 60ct plastic bottle, UPC #7-40985-21593-7
Elderberry Extract 60ct glass bottle, UPC #7-40985-21757-3

Respectfully submitted,

21st Century Laboratories, Inc.

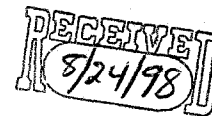
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Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula to Help Maintain Circulatory Efficiency to Lower Serum Cholesterol.

Dietary ingredient to which the statement refers: Odorless Garlic Extract and Cayenne Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Garlic Cayenne Extract 60ct plastic bottle, UPC #7-40985-21325-4.
Garlic Cayenne Extract 60ct glass bottle, UPC #7-40985-21727-6

Respectfully submitted,

21st Century Laboratories, Inc.

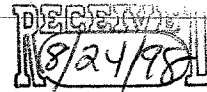
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Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula for Proper Support & Maintenance of Urinary Flow & Prostate Health in Men over 50.

Dietary ingredient to which the statement refers: Saw Palmetto Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Saw Palmetto Extract 60ct plastic bottle, UPC #7-40985-21228-8

Saw Palmetto Extract 60ct glass bottle, UPC #7-40985-21839-6

Saw Palmetto Extract 200ct plastic bottle, UPC #7-40985-21689-7

Saw Palmetto Extract Liquid 30ml glass bottle, UPC #7-40985-21681-1

Respectfully submitted,

21st Century Laboratories, Inc.

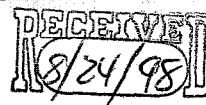
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Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula for Circulation, Swelling and Leg Vein Health

Dietary ingredient to which the statement refers: Horse Chestnut Seed Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Horse Chestnut Seed Extract 60ct plastic bottle, UPC #7-40985-21781-8.
Horse Chestnut Seed Extract 60ct glass bottle, UPC #7-40985-21805-1

Respectfully submitted,

21st Century Laboratories, Inc.

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Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula to Increase the Body's Natural Defenses During Cold & Flu Season

Dietary ingredient to which the statement refers: Echinacea Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Echinacea Extract 60ct plastic bottle, UPC #7-40985-21287-5
Echinacea Extract 60ct glass bottle, UPC #7-40985-21723-8
Echinacea Extract 200ct plastic bottle, UPC #7-40985-21691-0

Respectfully submitted,

21st Century Laboratories, Inc.

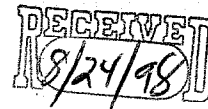
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Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula for Menstrual Discomfort.

Dietary ingredient to which the statement refers: Dong Quai Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Dong Quai Extract 60ct plastic bottle , UPC #7-40985-21375-9
Dong Quai Extract 60ct glass bottle, UPC #7-40985-21702-3
Dong Quai Extract Liquid 30ml glass bottle, UPC #7-40985-21678-1

Respectfully submitted,

21st Century Laboratories, Inc.

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Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula for Rest & Relaxation without Feeling Tired.

Dietary ingredient to which the statement refers: Kava Kava Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Kava Kava Extract 60ct plastic bottle, UPC #7-40985-21306-3
Kava Kava Extract 60ct glass bottle, UPC #7-40985-21807-5
Kava Kava Extract 200ct plastic bottle, UPC #7-40985-21952-2
Kava Kava Extract Liquid 30ml glass bottle, UPC #7-40985-21816-7

Respectfully submitted,

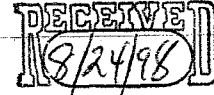
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Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula to Promote Restful Sleep.

Dietary ingredient to which the statement refers: Valerian Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Valerian Extract 60ct plastic bottle, UPC #7-40985-21305-6.
Valerian Extract 60ct glass bottle, UPC #7-40985-21827-3
Valerian Extract 200ct plastic bottle, UPC #7-40985-21933-1
Valerian Extract Liquid 30ml glass bottle, UPC #7-40985-21682-8

Respectfully submitted,

21st Century Laboratories, Inc.

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Dear Sirs,

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Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula for the Mind & Body

Dietary ingredient to which the statement refers: St. John's Wort Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

St. John's Wort Extract 60ct plastic bottle, UPC #7-40985-21312-4
St. John's Wort Extract 60ct glass bottle, UPC #7-40985-21851-8
St. John's Wort Extract 200ct plastic bottle, UPC #7-40985-21688-0
St. John's Wort Extract Liquid 30ml glass bottle, UPC #7-40985-21675-0

Respectfully submitted,

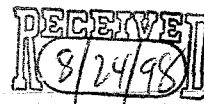
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Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula for Proper Support & Maintenance of Normal Liver Function.

Dietary ingredient to which the statement refers: Milk Thistle Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Milk Thistle Extract 60ct plastic bottle, UPC #7-40985-21338-4
Milk Thistle Extract 60ct glass bottle, UPC #7-40985-21864-8
Milk Thistle Extract Liquid 30ml glass bottle, UPC #7-40985-21686-6

Respectfully submitted,

21st Century Laboratories, Inc.

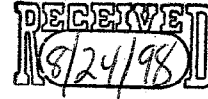
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Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula for General Health and Well Being.

Dietary ingredient to which the statement refers: Golden Seal Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Golden Seal Extract 60ct plastic bottle, UPC #7-40985-21296-7
Golden Seal Extract 60ct glass bottle, UPC #7-40985-21814-3

Respectfully submitted,

21st Century Laboratories, Inc.

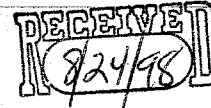
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Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula for Energy and Vitality.

Dietary ingredient to which the statement refers: Ginseng Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Ginseng Extract 60ct plastic bottle, UPC #7-40985-21300-1
Ginseng Extract 60ct glass bottle, UPC #7-40985-21802-0
Ginseng Extract 200ct plastic bottle, UPC #7-40985-21941-6
Ginseng Extract Liquid 30ml glass bottle, UPC #7-40985-21679-8

Respectfully submitted,

21st Century Laboratories, Inc.

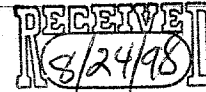
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Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): The Natural Choice for Joint and Bone Conditions.

Dietary ingredient to which the statement refers: Pure Shark Cartilage 500mg

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Shark Cartilage 500mg 30ct plastic bottle, UPC #7-40985-21229-5
Shark Cartilage 500mg 90ct plastic bottle, UPC #7-40985-21127-4
Shark Cartilage 500mg 200ct plastic bottle, UPC #7-40985-21500-5

Respectfully submitted,

21st Century Laboratories, Inc.

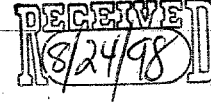
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Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): The Extra Strenght Formula in a 5:4 Ratio to Help Maintain the Natural Lubrication Found in Joints and Cartilage.

Dietary ingredient to which the statement refers: Glucosamine Sulfate and Chondroitin Sulfate.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Glucosamine Relief Extra Strength 60ct plastic bottle, UPC #7-40985-21854-9
Glucosamine Relief Extra Strength 150ct plastic bottle, UPC #7-40985-21868-6

Respectfully submitted,

21st Century Laboratories, Inc.

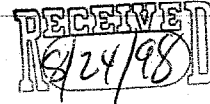
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Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): The Extra Strenght Formula to Help Maintain the Natural Lubrication Found in Joints and Cartilage.

Dietary ingredient to which the statement refers: Glucosamine Sulfate and Chondroitin Sulfate.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Glucosamine Relief 60ct plastic bottles, UPC #7-40985-21472-5
Glucosamine Relief 200ct plastic bottle, UPCC #7-40985-21690-3

Respectfully submitted,

21st Century Laboratories, Inc.

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Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Lose weight and eat the foods you enjoy with Chito-Lean.

Dietary ingredient to which the statement refers: Purified Chitosan

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Chito-Lean 60ct plastic bottle, UPC #7-40985-21587-6

Respectfully submitted,

21st Century Laboratories, Inc.

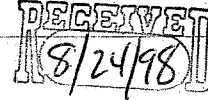
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Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula to Help Maintain a Healthy Urinary Tract

Dietary ingredient to which the statement refers: Cranberry Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Cranberry Extract 60ct plastic bottle, UPC #7-40985-21324-7
Cranberry Extract 60ct glass bottle, UPC #7-40985-21709-2

Respectfully submitted,

21st Century Laboratories, Inc.

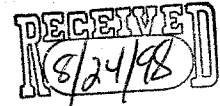
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Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula with Isoflavones for Nutritional Support During Menopause.

Dietary ingredient to which the statement refers: Black Cohosh Extract and Isoflavones

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Black Cohosh Extract 60ct plastic bottle, UPC #7-40985-21724-5.
Black Cohosh Extract 60ct glass bottle, UPC #7-40985-21858-7
Black Cohosh Extract 200ct plastic bottle, UPC #7-40985-21724-5
Black Cohosh Extract Liquid 30ml glass bottle, UPC #7-40985-21684-2

Respectfully submitted,

21st Century Laboratories, Inc.

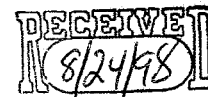
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Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula for Proper Vision and Nutrition for the Eyes.

Dietary ingredient to which the statement refers: Bilberry Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Bilberry Extract 60ct plastic bottle, UPC #7-40985-21345-2
Bilberry Extract 60ct glass bottle, UPC #7-40985-21696-5

Respectfully submitted,

21st Century Laboratories, Inc.

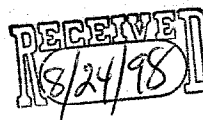
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Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): High Potency Herbal Formula to Improve Endurance and Mental Stamina.

Dietary ingredient to which the statement refers: Ginseng Extract and Energizing Herbal Blend of Guarana, Gotu Kola, Yerba Mate, Green Tea Extract, Ginger, Royal Jelly, Damiana and FoTi.

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Herbal Energy 60ct plastic bottle, UPC #7-40985-21647-7
Herbal Energy 60ct glass bottle, UPC #7-40985-21775-7

Respectfully submitted,

21st Century Laboratories, Inc.

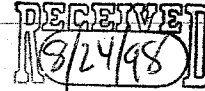
21ST Century Laboratories, Inc.

445 W. 12th Street, Unit 2, Tempe, Arizona 85281 U.S.A. • phone (602) 966-8201 • fax (602) 966-5395



4 August 1998

Office of Special Nutritionals (HFS-450)
FDA-CFSAN
200 C Street, S.W.
Washington, DC 20204



Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula to Support the Fight Against the Generation of Free Radicals.

Dietary ingredient to which the statement refers: Green Tea Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Green Tea Extract 60ct plastic bottle, UPC #7-40985-21592-0
Green Tea Extract 60ct glass bottle, UPC #7-40985-21823-5
Green Tea Extract Liquid 30ml glass bottle, UPC #7-40985-21685-9

Respectfully submitted,

21st Century Laboratories, Inc.

21ST Century Laboratories, Inc.

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4 August 1998



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Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Contains the highest levels of Resveratrol, Polyphenols, Anthocyanidins & Ellagic Acid for Cell Membrane Protection.

Dietary ingredient to which the statement refers: Grape Seed Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Grape Seed Extract 60ct plastic bottle, UPC #7-40985-21378-0.
Grape Seed Extract 60ct glass bottle, UPC #7-40985-21791-7
Grape Seed Extract 200ct plastic bottle, UPC #7-40985-21956-0

Respectfully submitted,

21st Century Laboratories, Inc.

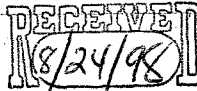
21ST Century Laboratories, Inc.



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200 C Street, S.W.
Washington, DC 20204



Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula for Memory and Fatigue.

Dietary ingredient to which the statement refers: Gotu Kola Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Gotu Kola Extract 60ct plastic bottle, UPC #7-40985-21311-7
Gotu Kola Extract 60ct glass bottle, UPC #7-40985-21784-9

Respectfully submitted,

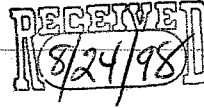
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Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula to Improve Memory, Concentration & Mental Performance.

Dietary ingredient to which the statement refers: Ginkgo Biloba Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Ginkgo Biloba Extract 60ct plastic bottle, UPC #7-40985-21249-3
Ginkgo Biloba Extract 60ct glass bottle, UPC #7-40985-21771-9
Ginkgo Biloba Extract 200ct plastic bottle, UPC #7-40985-21687-3
Ginkgo Biloba Extract Liquid 30ml glass bottle, UPC #7-40985-21680-4

Respectfully submitted,

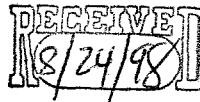
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Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula to Promote Proper Digestion and Circulation

Dietary ingredient to which the statement refers: Ginger Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Ginger Extract 60ct plastic bottle, UPC #7-40985-21317-9
Ginger Extract 60ct glass bottle, UPC #7-40985-21749-8

Respectfully submitted,

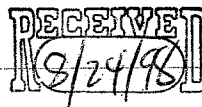
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Washington, DC 20204

Dear Sirs,

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement to which that section refers.

Manufacturer's name and address: 21st Century Laboratories, Inc. 2445 W. 12th Street #2, Tempe, AZ 85281.

Statement(s): Maximum Strength Formula for Normal Blood Vessel Tone.

Dietary ingredient to which the statement refers: Feverfew Extract

Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Feverfew Extract 60ct plastic bottle, UPC #7-40985-21315-5
Feverfew Extract 60ct glass bottle, UPC #7-40985-21743-6

Respectfully submitted,

21st Century Laboratories, Inc.