

#### **DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service** 

Food and Drug Administration Washington, DC 20204

4356 'DI MAY 15 P2:30

APR | 3 2001

President 21st Century Laboratories, Inc. 2 119 South Wilson Street Tempe, Arizona 85282-2034

Dear Sir/Madam:

This is in response to **your** submissions to the Food and Drug Administration (FDA), dated April 5,200 1. Your submissions appear to be 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 submissions do not meet this requirement in that the notices do contain the signature of a **responsible** individual nor do they 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).

Please contact us if we may be of further assistance.

Sincerely,

Im B Fact John B. Foret

Director Division of Compliance and Enforcement Office of Nutritional Products, Labeling, and Dietary Supplements Center for Food Safety and Applied Nutrition

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Page 2 - 21 st Century Laboratories

Copies:

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FDA, Center for Drug Evaluation and Research, Offke 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



2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300

4/5/01

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: 21 st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

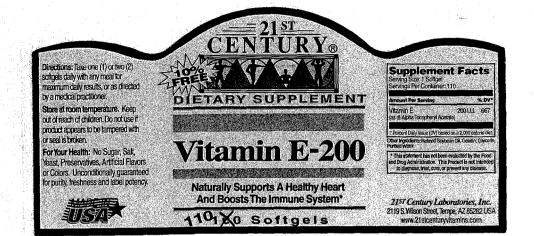
Statement(s): Naturally Supports A Healthy Heart **And** Boosts The Immune System. (and) Vitamin E 200 (dl-Alpha Tocopheryl Acetate) is an essential antioxidant nutrient **that** helps maintain red blood cells and muscle tissue such as cardiac and skeletal muscles. Helps to protect the HDL Cholesterol (good) from oxidation which may cause cellular damage.

Dietary ingredient(s) to which the statement refers: Vitamin E (dl-Alpha Tocopheryl Acetate).

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

Vitamin E-200 11 Oct, UPC #7-40985-21302-5

Respectfully submitted,





21st Century's<sup>®</sup> Vitamin E-200 (dl-Alpha Tocopheryl Acetate) is an essential antioxidant nutrient that helps maintain red blood ceils and muscle tissue such as cardiac and skeletal muscles. Helps to protect the HDL Cholesterol (good) from oxidation which may cause cellular damage.\*

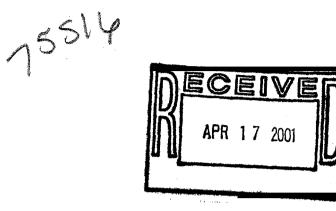


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2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300

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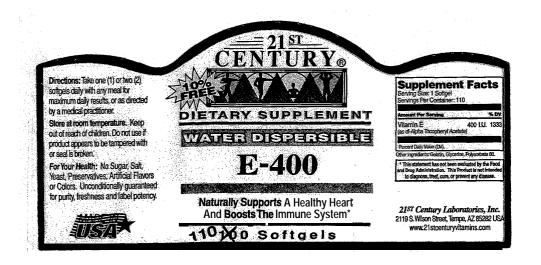
Statement(s): Naturally Supports A Healthy Heart And Boosts The Immune System. (and) Water Dispersible Vitamin E 400 (dl-Alpha Tocopheryl Acetate) is an essential antioxidant nutrient that helps maintain red blood cells and muscle tissue such as cardiac and skeletal muscles. Helps to protect the HDL Cholesterol (good) from oxidation which may cause cellular damage.

Dietary ingredient(s) to which the statement refers: Vitamin E (dl-Alpha Tocopheryl Acetate).

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

Water Dispersible Vitamin E-400 1 10ct, UPC #7-40985-22558-5

Respectfully submitted,



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21<sup>57</sup> Century's...tor a healthier future. Water Dispersible E-400 21st Century's@ Water Dispersible Vitamin E-400 (dl-Alpha Tocopheryl Acetate) is an essential antioxidant nutrient that helps maintain red blood cells and muscle tissue such as cardiac and skeletal muscles. Helps to protect the HDL Cholesterol (good) from oxidation which may cause cellular damage.



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4/5/01

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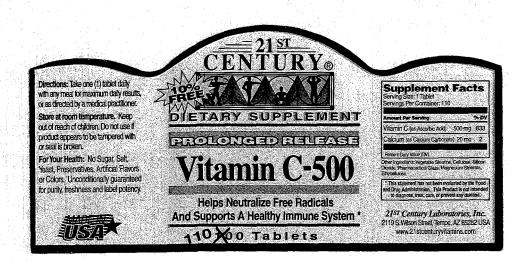
Statement(s): Helps Neutralize Free Radicals And Supports A Healthy Immune System. (and) Vitamin C is an important antioxidant nutrient that helps **netralize free** radicals which may cause cellular damage in the body

Dietary ingredient(s) to which the statement refers: Vitamin C (Ascorbic Acid).

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

Prolonged Release Vitamin C 500 11 Oct, UPC #7-40985-21190-8

Respectfully submitted,





21" Century... for a healthier future. Vitamin C -500 Vitamin C is an important antioxidant nutrient that helps neutralize free radicals which may cause cellular damage in the body. Vitamin C also supports a healthy immune system.' 21st Century's<sup>a</sup> prolonged release Vitamin C-500 provides long-term vitamin supplementation by slowly releasing nutrients to the body over an extended period of time.

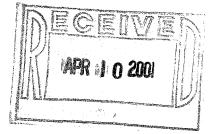


# 21 ST Century Laboratories, Inc.

2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300

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



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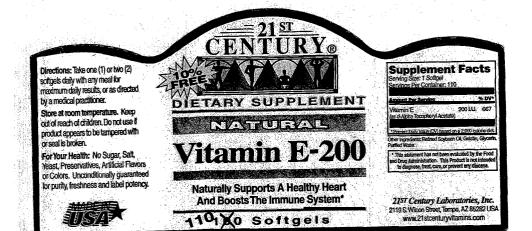
Statement(s): Naturally Supports A Healthy Heart And Boosts The Immune System. (and) Natural Vitamin E 200 (d-Alpha Tocopheryl Acetate) is an essential antioxidant nutrient that helps maintain red blood cells and muscle tissue such as cardiac and skeletal muscles. Helps to protect the HDL Cholesterol (good) from oxidation which may cause cellular damage.

Dietary ingredient(s) to which the statement refers: Vitamin E (d-Alpha Tocopheryl Acetate).

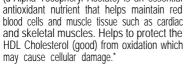
Name of the supplement bearing the label or associated with the labeling: 21st Century Laboratories, Inc.,

Natural Vitamin E-200 1 10ct, UPC #7-40985-22347-5

Respectfully submitted,









2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. phone 480-966-8201 • fax 480-927-9300

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4/5/01

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



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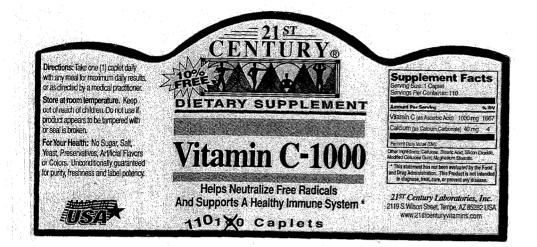
Statement(s): Helps Neutralize Free Radicals And Supports A Healthy Immune System. (and) Vitamin C is an important antioxidant nutrient that **helps netralize free** radicals which may cause cellular damage in the body

Dietary ingredient(s) to which the statement refers: Vitamin C (Ascorbic Acid).

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

Vitamin C 1000 1 10ct, UPC #7-40985-22433-5

Respectfully submitted,





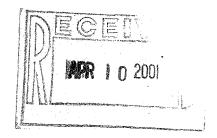
Vitamin C is an important antioxidant nutrient that helps neutralize free radicals which may cause cellular damage in the body. Vitamin C also supports a healthy immune system.\*



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4/5/01

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



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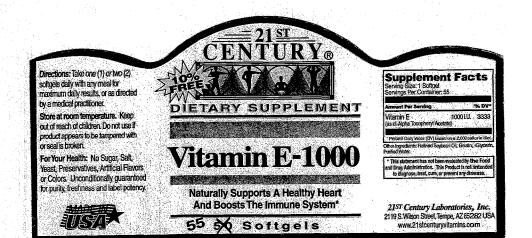
Statement(s): Naturally Supports A Healthy Heart And Boosts The Immune System. (and) Vitamin E 1000 (dl-Alpha Tocopheryl Acetate) is an essential antioxidant nutrient that helps maintain red blood cells and muscle tissue such as cardiac and skeletal muscles. Helps to protect the HDL Cholesterol (good) **from** oxidation which may cause cellular damage.

Dietary ingredient(s) to which the statement refers: Vitamin E (dl-Alpha Tocopheryl Acetate).

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

Vitamin E- 1000 11 **Oct**, UPC **#7-40985-22324-6** 

Respectfully submitted,





21st Century's@ Vitamin E-1000 (dl-Alpha Tocopheryl Acetate) is an essential antioxidant nutrient that helps maintain red blood ceils and muscle tissue such as cardiac and skeletal muscles. Helps to protect the HDL Cholesterol (good) from oxidation which, may cause cellular damage.\*



2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300



4/5/01

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



Dear Sirs,

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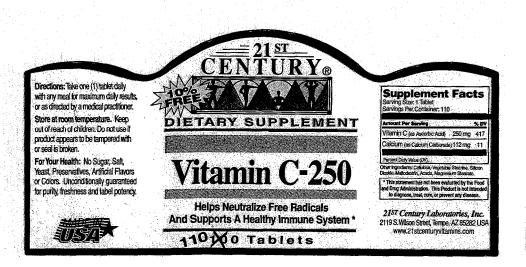
Statement(s): Helps Neutralize Free Radicals And Supports A Healthy Immune System. (and) Vitamin C is an important antioxidant nutrient that helps **netralize free** radicals which may cause cellular damage in the body

Dietary ingredient(s) to which the statement refers: Vitamin C (Ascorbic Acid).

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

Vitamin C 250 1 10ct, UPC #7-40985-22294-2

#### Respectfully submitted,





Vitamin C is an important **antioxidant** nutrient that helps neutralize free radicals which may cause cellular damage in the body. Vitamin C also supports a healthy immune system.\*





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4/5/01

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Manufacturer's name and address: 21st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Helps Neutralize Free Radicals And Supports A Healthy Immune System. (and) Vitamin C is an important antioxidant nutrient that helps **netralize free** radicals which may cause cellular damage in the body

Dietary ingredient(s) to which the statement refers: Vitamin C (Ester C tm Calcium Ascorbate).

Name of the supplement bearing the label or associated with the labeling: 2 1st Century Laboratories, Inc.,

Ester C 500 66ct, UPC #7-40985-22561-5

Respectfully submitted,





Vitamin C is an important a&oxidant nutrient that helps neutralize free radicals which may cause cellular damage in the body. Vitamin C **also** supports a healthy immune system.



2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300

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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: 21 st Century Laboratories, Inc. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): Naturally Supports A Healthy Heart And Boosts The Immune System (and) Natural Vitamin E 400 (d-Alpha Tocopheryl Acetate) is an essential antioxidant nutrient that helps maintain red blood cells and muscle tissue such as cardiac and skeletal muscles. Helps to protect the HDL Cholesterol (good) from oxidation which may cause cellular damage.

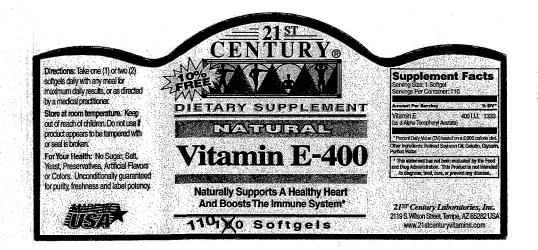
Dietary ingredient(s) to which the statement refers: Vitamin E (d-Alpha Tocopheryl Acetate).

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

Natural Vitamin E-400 11 Oct, UPC #7-40985-22343-7

Respectfully submitted,







21st Century's@ Natural Vitamin E-400 (d-Alpha Tocopheryl Acetate) is an essential antioxidant nutrient that helps maintain red blood cells and muscle tissue such as cardiac and skeletal muscles. Helps to protect the HDL Cholesterol (good) from oxidation which may cause cellular damage.'



2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300

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

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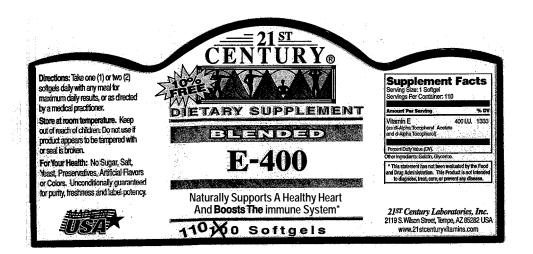
Statement(s): Naturally Supports A Healthy Heart And Boosts The Immune System. (and) Blended Vitamin E 400 (dl-Alpha Tocopheryl Acetate and d-Alpha Tocopheryl Acetate) is an essential antioxidant nutrient that helps maintain red blood cells and muscle tissue such as cardiac and skeletal muscles. Helps to protect the HDL Cholesterol (good) from oxidation which may cause cellular damage.

Dietary ingredient(s) to which the statement refers: Vitamin E (dl-Alpha Tocopheryl Acetate and d-Alpha Tocopheryl Acetate).

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

Blended Vitamin E-400 1 **10ct**, UPC **#7-40985-22560-8** 

Respectfully submitted,



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**21st** Century's@ Blended Vitamin E-400 (dl-Alpha **Tocopheryl** Acetate and d-Alpha Tocopherol) is an essential antioxidant nutrient that helps maintain red blood cells and muscle tissue such as **cardiac** and skeletal muscles. Helps to protect the HDL Cholesterol (good) from oxidation which may cause cellular damage.



21 lb South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300

4/5/01

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APR 1 0 2001

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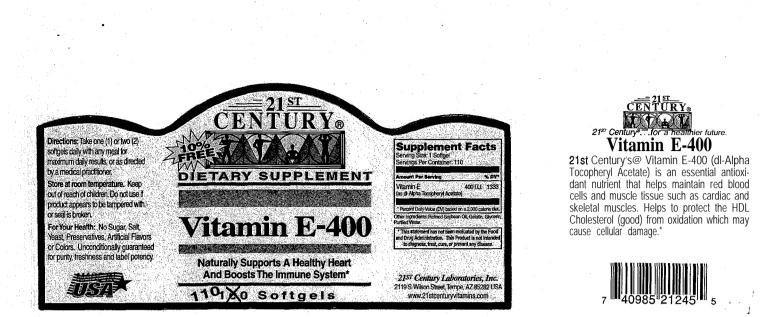
Statement(s): Naturally Supports A Healthy Heart And Boosts The Immune System (and) Vitamin E 400 (**dl-Alpha** Tocopheryl Acetate) is an essential antioxidant nutrient that helps maintain red blood cells and muscle tissue such as cardiac and skeletal muscles. Helps to protect the HDL Cholesterol (good) from oxidation which may cause cellular damage.

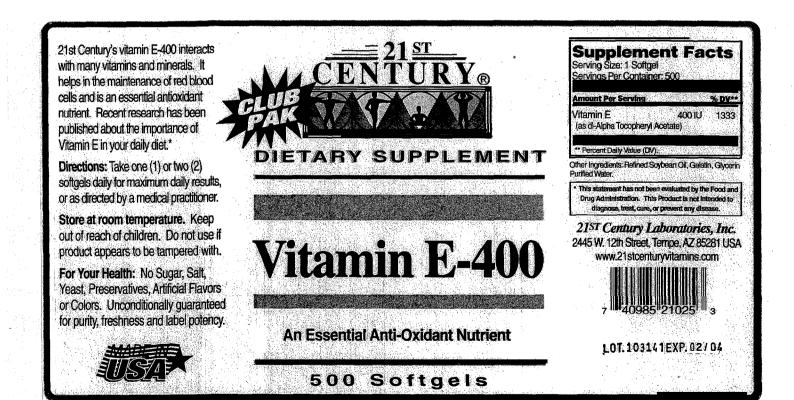
Dietary ingredient(s) to which the statement refers: Vitamin E (dl-Alpha Tocopheryl Acetate).

Name of the supplement bearing the label or associated with the labeling: 2 1st Century Laboratories, Inc.,

Vitamin E-400 **11 Oct**, UPC **#7-40985-2** 1245-5 Vitamin E-400 **500ct**, UPC **#7-40985-21025-3** 

Respectfully submitted,







2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300

4/5/01

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

APR 102001

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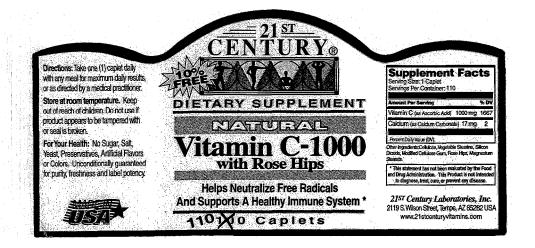
Statement(s): Helps Neutralize Free Radicals And Supports A Healthy Immune System (and) Vitamin C is an important antioxidant nutrient that helps **netralize** free radicals which may cause cellular damage in the body.

Dietary ingredient(s) to which the statement refers: Vitamin C (Ascorbic Acid), Rose Hips.

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

Vitamin C 1000 with Rose Hips 1 10ct, UPC #7-40985-22383-3

#### Respectfully submitted,





Vitamin C is an important antioxidant nutrient that helps neutralize free radicals which may cause cellular damage in the body. Vitamin C also supports a healthy immune system.\* 21st Century's Vitamin C-1000 contains Rose Hips an excellent natural source of Vitamin C.



s Principality



2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300

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Office of Special Nutritionals (HFS-450) FDA-CFSAN 200 C Street, **S.W.** Washington, DC 20204 APR 1 0 2001 BY:\_\_\_\_

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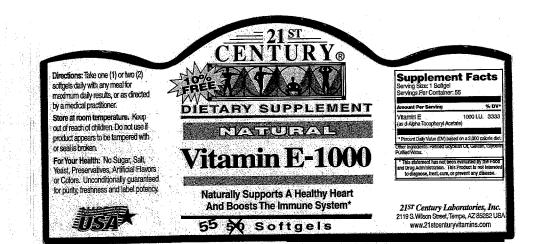
Statement(s): Naturally Supports A Healthy Heart And Boosts The Immune System (and) Natural Vitamin E 1000 (d-Alpha Tocopheryl Acetate) is an essential antioxidant nutrient that helps maintain red blood cells and muscle tissue such as cardiac and skeletal muscles. Helps to protect the HDL Cholesterol (good) from oxidation which may cause cellular damage.

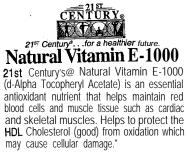
Dietary ingredient(s) to which the statement refers: Vitamin E (d-Alpha Tocopheryl Acetate).-

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

Natural Vitamin E-1 000 11 **Oct**, UPC **#7-40985-22339-0** 

Respectfully submitted,







2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300

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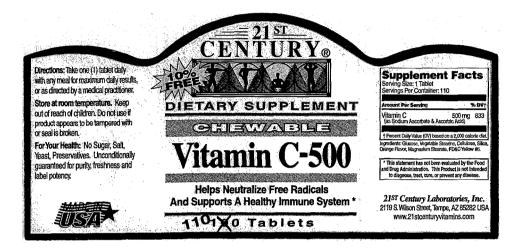
Statement(s): Helps Neutralize Free Radicals And Supports A Healthy Immune System. (and) Vitamin C is an important antioxidant nutrient that helps **netralize** free radicals which may cause cellular damage in the body

Dietary ingredient(s) to which the statement refers: Vitamin C (Ascorbic Acid).

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

Chewable Vitamin C 500 11 Oct, UPC #7-40985-2 1024-6

Respectfully submitted,



3



Vitamin C is an important antioxidant **nutrient** that helps neutralize free radicals which may cause cellular damage in the body. Vitamin C also supports a healthy immune system.' These delicious orange flavored chewable tablets are formulated for those who prefer to chew their Viin C to increase assimilation



2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300

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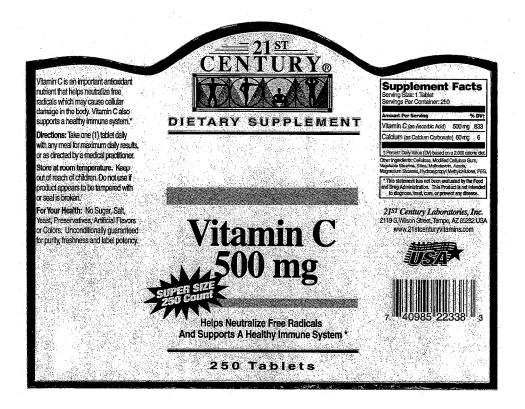
Statement(s): Helps Neutralize Free Radicals And Supports A Healthy Immune System. (and) Vitamin C is an important antioxidant nutrient that helps **netralize** free radicals which may cause cellular damage in the body

Dietary ingredient(s) to which the statement refers: Vitamin C (Ascorbic Acid).

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

Vitamin C 500 250ct, UPC #7-40985-22338-3

Respectfully submitted,



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2119 South Wilson Street, Tempe, Arizona 85282-2034 U.S.A. • phone 480-966-8201 • fax 480-927-9300

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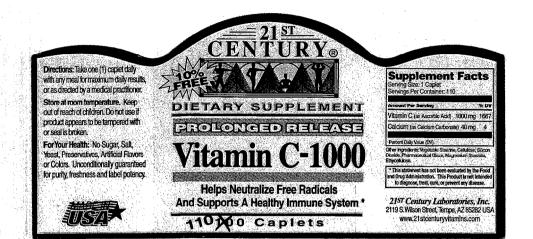
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Dietary ingredient(s) to which the statement refers: Vitamin C (Ascorbic Acid).

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

Prolonged Release Vitamin C 1000 11 Oct, UPC #7-40985-21225-7

Respectfully submitted,



Ĵ,



Vitamin C is an important antioxidant nutrient that helps neutralize free radicals which may cause cellular damage in the body. Vitamin C also supports a healthy immune system.\*21stCenturyse prolonged release Vitamin C-1000 provides long-term vitamin supplementation by slowly releasing nutrients to the body over an extended period of time.



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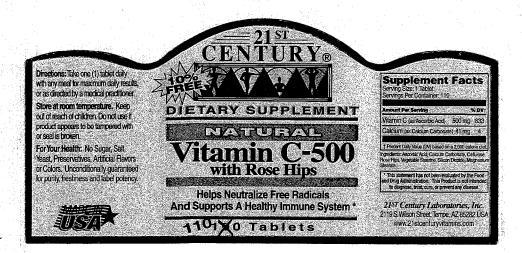
Statement(s): Helps Neutralize Free Radicals And Supports A Healthy Immune System. (and) Vitamin C is an important antioxidant nutrient that helps **netralize** free radicals which may cause cellular damage in the body . (and) Vitamin C is an essential **Anti-**Oxidant nutrient.

Dietary ingredient(s) to which 'the statement refers: Vitamin C (Ascorbic Acid), Rose Hips.

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

Vitamin C 500 with Rose Hips110ct, UPC #7-40985-21002-4 Vitamin C 500 with Rose Hips1000ct, UPC #7-40985-21273-8

Respectfully submitted,





**C-500 with Rose Hips** Vitamin C is an important **antioxidant** nutrient that helps neutralize free radicals which may cause cellular damage in the body. Vitamin C also supports a healthy immune system.\* **21st** Century's Vitamin C-500 with Rose Hips is an excellent natural source of Vitamin C.

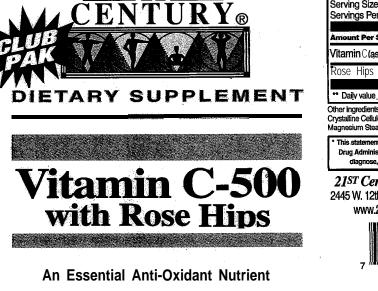


Viin C is an essential anti-oxidant nutrient 21st Century's VITAMINC-500 with Rose Hips is an excellent source of Vitamin C.\*

Directions: Take one (1) tablet daily with any meal for maximum daily results, or as directed by a medical practitioner.

Store at room temperature. Keep out of reach of **children.** Do not use if product appears to be tampered with.

For Your Health: No Sugar, Salt, Yeast, **Preservatives**, Artificial **Flavors** or Colors. **Unconditionally guaranteed** for purity, freshness and label potency.



Tablets

1000



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