



MAY 20 2003

2761 '03 MAY 28 P2:35

Mr. Steve Snyder  
President  
21<sup>st</sup> Century Nutritional Products, Inc.  
2119 South Wilson Street  
Tempe, Arizona 85282-2034

Dear Mr. Snyder:

This is in response to your submission to the Food and Drug Administration (FDA), dated April 28, 2003. Your submission appears 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 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). The failure to submit a valid notice as required by the Act and the agency's regulation may subject your product to regulation under the drug provisions of the Act.

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

975-0163

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**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

# 21<sup>ST</sup> Century Laboratories, Inc.

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



4/28/03

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. 2119 S. Wilson Street, Tempe, AZ 85282.

Statement(s): To help relieve stress and frustration. For self-confident mood and cheerful outlook. Relora 375 has been shown to be an effective natural non-sedating herbal extract that helps control occasional mild anxiety, restlessness, emotional ups and downs, irritability, tense muscles, poor sleep and concentration difficulties. Relora 375 reduces stress, the health risks related to stress and normalizes hormone levels.

Dietary ingredient(s) to which the statement refers: Relora tm (a proprietary blend of the extracts of Magnolia officinalis bark and Phellodendron amurense bark)

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

Relora 375 60 count vegetarian formula, UPC #7-40985-22807-4

Relora 375 60 count regular formula, UPC #7-40985-22752-7

Relora 375 90 count regular formula, UPC #7-40985-22750-3

Respectfully submitted,

21st Century Laboratories, Inc.

### Rose Colored Glasses In A Bottle™

Relora 375 has been shown to be an effective natural non-sedating herbal extract that helps control occasional mild anxiety, restlessness, emotional ups and downs, irritability, tense muscles, poor sleep and concentration difficulties.\* Relora 375 reduces stress, the health risks related to stress and normalizes hormone levels.\* **SATISFACTION GUARANTEED**

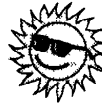
**Directions:** Take two (2) capsules daily – one (1) in the morning and one (1) in the afternoon with meals, or as directed by a physician.

**Caution:** Not intended for use by persons under 18 years of age. Discontinue use if adverse reactions occur. If problem persists consult your physician. If pregnant, nursing or taking a prescription drug, consult a medical practitioner prior to use. Do not exceed recommended dosage. Excessive consumption may impair ability to drive or operate heavy equipment. Not recommended for consumption with alcoholic beverages. Store at room temperature. Keep out of reach of children. Do not use if product appears to be tampered with or seal is broken. For Your Health: No Added Sugar, Salt, Yeast, Preservatives or Artificial Flavors. Unconditionally guaranteed for purity, freshness and label potency.



# Relora<sup>375</sup>

**ANTI-ANXIETY FORMULA**



*To Help Relieve Stress & Frustration\*  
For Self-Confident Mood & Cheerful Outlook\**

Dietary Supplement — 60 Vegetarian Capsules

**30-Day Supply • All Natural**

### Supplement Facts

Serving Size: 2 Vegetarian Capsules  
Servings Per Container: 30

Amount Per Serving	% DV
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Relora® Proprietary Blend†	750 mg **
A patent pending blend of plant extracts from <i>Magnolia officinalis</i> (bark) & <i>Phellodendron amurense</i> (bark)	

\*\* Daily Value (DV) not established.

Other Ingredients: Vegetable Cellulose, Rice Bran, Oat Fiber, Magnesium Stearate, Magnesium Silicate, Silicon Dioxide.

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

Relora® is a trademark of Next Pharmaceuticals, Inc.



21st Century HealthCare, Inc.  
2119 S. Wilson St., Tempe AZ 85282 U.S.A.  
1-800-530-21ST (2178) www.21stcenturyvitamins.com

Bottle: 150cc/175cc  
Diameter: 2.25" x 6.75"  
Stock: Foil Label  
Inks: 3-Color Process  
Black Line  
PMS 2415 (Purple)  
Opaque White (min 2 hits)

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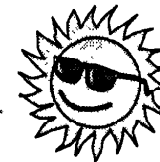
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**Caution:** Not intended for use by persons under 18 years of age. Discontinue use if adverse reactions occur. If problem persists consult your physician. If pregnant, nursing or taking a prescription drug, consult a medical practitioner prior to use. Do not exceed recommended dosage. Excessive consumption may impair ability to drive or operate heavy equipment. Not recommended for consumption with alcoholic beverages. Store at room temperature. Keep out of reach of children. Do not use if product appears to be tampered with or seal is broken. For Your Health: No Added Sugar, Salt, Yeast, Preservatives or Artificial Flavors. Unconditionally guaranteed for purity, freshness and label potency.



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