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AUG - 3 2001

Mr. Mark F. Sever  
President  
European Lifestyle Products, LLC  
P.O. Box 1345  
Gibsonia, Pennsylvania 15044

Dear Mr. Sever:

This is in response to your letter to the Food and Drug Administration (FDA), dated July 27, 2001, 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 European Lifestyle Products, LLC is making the following claims, among others, for the product **RED NOSE™**:

- “Reduce the effects of a hangover”
- “Feel better in the morning”
- “...eases the pain of hangovers”
- “...subject of numerous alcohol-related studies...reduces the urge to drink and mitigates the negative effects of alcohol in laboratory animals...rats fed kudzu drank less and were less intoxicated...refer to the university web site at [www.med.unc.edu/alcohol](http://www.med.unc.edu/alcohol) and search...for detailed information on the studies and results...referenced by the California Drunk Driving web site”
- “Make your last drink a RED NOSE™ and feel better in the morning.”

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 this product suggest that it is intended to treat, prevent, or mitigate disease, namely alcohol intoxication or toxicity. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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.

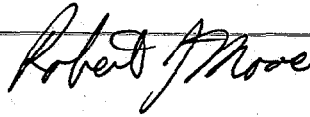
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Page 2 - Mr. Mark F. Sever

Please contact us if we may be of further assistance.

Sincerely,



for

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

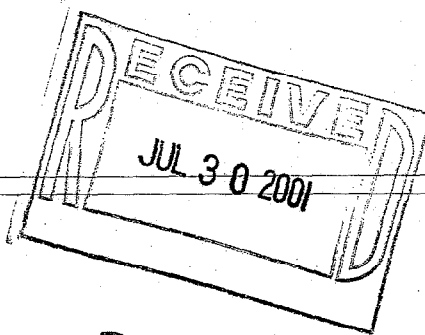
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Philadelphia District Office, Compliance Branch, HFR-MA140

Overnight Mail

July 27, 2001

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, S.W.  
Washington D.C. 20204



77082

Ref: RED NOSE™ Herbal Supplement

Dear Sir and/or Madam:

This is a notification pursuant to Section 403(r)(6)(C) of the Federal Food, Drug, and Cosmetic Act that European Lifestyle Products, LLC, Gibsonia, Pennsylvania 15044, has, within the past 30 days, begun marketing its hangover relief product "RED NOSE™" using the following statements:

1) On Product Label:

- a) "Reduce the effects of a hangover" and
- b) "Feel better in the morning"

2) In Promotional Labeling:

- a) Contains two plant extracts well-known and used as herbal supplements in Asia for centuries:
  - i) Kudzu root (technically Puerariae Radix, in Chinese Ge Gen).
  - ii) Chrysanthemum flower (technically Chrysanthemi Flos, in Chinese Ju Hua).
- b) Search these names over the Internet to discover their interesting history.
- c) People in China have long held that kudzu eases the pain of hangovers.
- d) The kudzu root has been the subject of numerous alcohol-related studies by the scientific community. At The Bowles Center for Alcohol Studies at The University of North Carolina at Chapel Hill researchers have studied kudzu extensively and stated that a kudzu-based Chinese herbal medicine

**P.O. Box 1345 Gibsonia, PA 15044 724-934-3068 FAX 724-934-9181**


reduces the urge to drink and mitigates the negative effects of alcohol in laboratory animals. They further stated that rats fed kudzu drank less and were less intoxicated. Refer to the university web site at [www.med.unc.edu/alcohol](http://www.med.unc.edu/alcohol) and search the word "kudzu" for detailed information on the studies and results. This study is even referenced by the California Drunk Driving web site [www. DUI.com](http://www. DUI.com) under item 50 in the Alcohol Issues section.

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- e) The combination of herbs and flavorings make RED NOSE™ a satisfying last drink. "Make your last drink a RED NOSE™, and feel better in the morning."
- f) Ingredient Statement: These statements are made for an herbal supplement containing a proprietary blend of kudzo root extract and chrysanthemum flower extract. Other ingredients include citric acid anhydrous, sodium bicarbonate, modified potato starch, lemon flavor, lime flavor, sodium cyclamate, sodium saccharinate dyhydrate, sorbitol powder, and vitamin B2-5-sodium phosphate dihydrate.

The information contained herein is a complete and accurate representation of the product named. European Lifestyle Products, LLC has substantiation of the statements of nutritional support based on scientific literature which render those statements truthful and not misleading.

Sincerely,



Mark F. Sever  
President

Directions: After your last drink or at bedtime dissolve one (1) tablet in a glass of water.

Supplement Facts: Serving size: One (1) tablet. Amount per serving: Calories 9, Fat Cal. 0, Total Carb. 1g (0% DV), Sugars 1g, Sodium 1300mg (54% DV), Vitamin C (as ascorbic acid) 60mg (100% DV), Kudzu Root (Ge Gen-Radix Puerariae) Extract 600mg\*, Chrysanthemum Flower (Ju Hua-Chrysanthemi Flos) Extract 400mg\*. Percent Daily Values are based on a 2,000 calorie diet.

\*Daily Value not established.

Other Ingredients: Citric acid anhydrous, sodium bicarbonate, modified potato starch, lemon flavor, lime flavor, sodium cyclamate, sodium saccharinate dihydrate, sorbitol powder, and vitamin B2-5-sodium phosphate dihydrate.

[www.europeanlifestyleproducts.com](http://www.europeanlifestyleproducts.com)

Distributed by  
European Lifestyle Products, LLC  
P.O. Box 1345, Gibsonia, PA 15044

Made in Switzerland



MAKE YOUR LAST DRINK A  
**RED NOSE™**  
\* "The after party tab"



Herbal Supplement | Tablet 4.5g

Foil Pack - Actual Size

# RED NOSE

*"The after party tab!"*

- Contains two plant extracts well-known and used as herbal supplements in Asia for centuries:
  - Kudzu root (technically Puerariae Radix, in Chinese Ge Gen).
  - Chrysanthemum flower (technically Chrysanthemi Flos, in Chinese Ju Hua).
- Search these names over the Internet to discover their interesting history.
- People in China have long held that Kudzu eases the pain of hangovers.
- The Kudzu root has been the subject of numerous alcohol-related studies by the scientific community. At The Bowles Center for Alcohol Studies at The University of North Carolina at Chapel Hill researchers have studied Kudzu extensively and stated that a Kudzu-based Chinese herbal medicine reduces the urge to drink and mitigates the negative effects of alcohol in laboratory animals. They further stated that rats fed Kudzu drank less and were less intoxicated. Refer to the university web site at [www.med.unc.edu/alcohol](http://www.med.unc.edu/alcohol) and search the word "kudzu" for detailed information on the studies and results. This study is even referenced by the California Drunk Driving web site [www.dui.com](http://www.dui.com) under item 50 in the Alcohol Issues section.
- The combination of herbs and flavorings make RED NOSE a satisfying last drink. *"Make your last drink a RED NOSE, and feel better in the morning."*

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.

Product Bin Display  
Approx 80% of Actual Size

Too Much  
Partying? Try  
**RED NOSE**<sup>TM</sup>

"Reduce the effects of a hangover  
and feel better in the morning"\*

\*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.

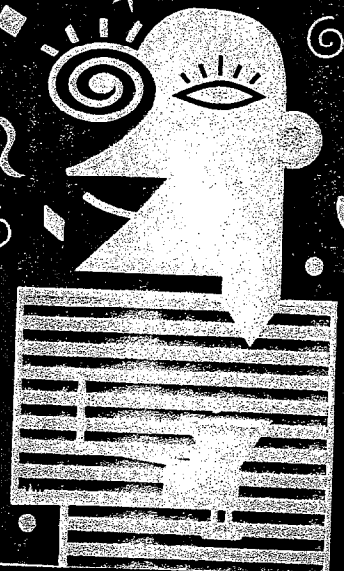
MAKE YOUR LAST DRINK A  
**RED NOSE**<sup>TM</sup>

"The after party tab"



Too Much  
Partying? Try  
**RED NOSE**<sup>TM</sup>

"Reduce the effects of a hangover  
and feel better in the morning"\*



MAKE YOUR LAST DRINK A  
**RED NOSE™**

"The after party tab"

**Supplement Facts**

Serving Size 1 Tablet

Amount Per Tablet

Calories 9      Calories from Fat 0

% Daily Value

Total Fat 0g

Total Carbohydrate 1g      0%\*

Sugars 1g

Sodium 1,300 mg      54%\*

Vitamin C

(as ascorbic acid) 60 mg      100%\*

Kudzu Root Extract 600 mg      †

(Ge Gen Radix Puerariae)

Chrysanthemum Flower

Extract 400mg      †

(Ju Hua Chrysanthemi Flos)

\* Percent Daily Values are based on a 2,000 calorie diet.

† Daily Value not established.

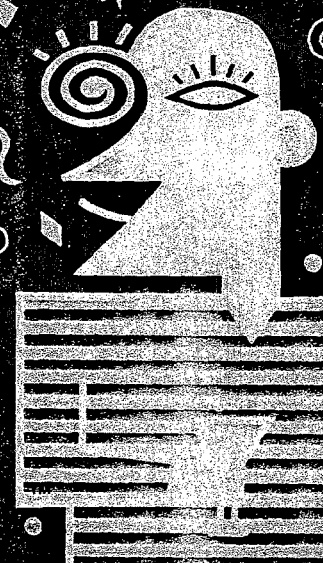
Other Ingredients: Citric acid anhydrous, sodium bicarbonate, modified potato starch, lemon flavor, lime flavor, sodium cyclamate, sodium saccharate dihydrate, sorbitol powder and vitamin B2-5-sodium phosphate dihydrate

Herbal Supplement  
**50 Tablets**

Distributed by  
 European Lifestyle Products, LLC  
 P.O. Box 1345  
 Gibsonia, PA 15044  
 Made in Switzerland

Too Much  
 Partying? Try  
**RED NOSE™**

"Reduce the effects of a hangover  
 and feel better in the morning"\*



VISIT [WWW.EUROPEANLIFESTYLEPRODUCTS.COM](http://WWW.EUROPEANLIFESTYLEPRODUCTS.COM)

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