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NOV 28 2006

Mr. Peter Sewell
Director of Product Development
Tronex Company
One Tronex Centre
2 Cranberry Road
Parsippany, New Jersey 07054

Dear Mr. Sewell:

This is in response to your letter of October 31, 2006 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) for the products Trimnastics Tea and Beautysleep.

You made a submission for the product Trimnastics Tea. 21 U.S.C. 321(ff) defines the term "dietary supplement." As defined by the Act, a dietary supplement does not include a product represented for use as a conventional food or as a sole item of a meal or the diet. 21 U.S.C. 321(ff)(2)(B). The product identified above appears to be represented for use as a conventional food (i.e., it is identity labeled as a "Natural Herbal Drink." Therefore, in that it appears to be represented for use as a conventional food (i.e., a drink or beverage), it does not appear to be a dietary supplement within the meaning of 21 U.S.C. 321(ff) and claims made for it are not subject to 21 U.S.C. 343(r)(6). Instead, this product appears to be a conventional food that must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, it must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the product in its labeling if they are claims defined by 21 U.S.C. 343(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to market this product as a conventional food and you have any questions about the status of any of its ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

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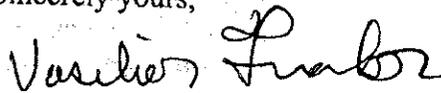
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In your submission for the product Beautysleep, you represent that it "[H]elps you enjoy good sleep naturally without taking the risk of prescription drugs dependency." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000), FDA stated that claims such as "Helps you fall asleep if you have difficulty falling asleep" and "helps to reduce difficulty falling asleep" are disease claims, unless the context makes clear that the product is only for occasional sleeplessness, because they imply treatment of insomnia, a disease. (See 65 FR 1000 at 1031). FDA also stated that, in some cases, to determine whether a product name implies an effect on disease, the agency will need to consider the context in which a term is presented in the labeling as a whole. For example, a product named "Soothing Sleep" could be considered a claim to treat insomnia, unless the labeling made clear that the product was intended only for occasional sleeplessness. (See 65 FR 1000 at 1022). FDA further stated that section 403(r)(6) of the act does not permit a dietary supplement manufacturer to claim that its product has fewer side effects than a drug, if the drug is intended to treat or prevent disease, because the clear implication is that the dietary supplement is intended for treatment or prevention of the same disease. (See 65 FR 1000 at 1028). Your product name, its claims to promote sleep, and its claim to promote sleep without the use of prescription drugs imply that it is intended to treat insomnia or sleeping difficulties, conditions which are diseases within the meaning of 21 CFR 101.93(g).

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. 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Please contact us if you require further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, New Jersey District Compliance, HFR-CE340

TRONEX

Date: October 31, 2006.

Dr. Robert Moore, Branch Chief,
Compliance and Enforcement Branch
Division of Dietary Supplement Program/ONPLDS
Center for Food Safety and Applied Nutrition
Food and Drug Administration
HFS-801
200 C Street, SW
Washington, DC 20204



Subject: 30 Day Notification letter of Dietary Supplement's Statement

Dear Dr. Moore,

As the authorized U.S. Agent and Principal distributor for Wellslife Corporation (Taiwan), with registered Company address at 2 Cranberry road, Parsippany, NJ07054, notice is hereby given pursuant to the requirements of Section 403(r)(6) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 343(r)(6)) of the intent of use to market in the U.S. dietary supplements, brand-named as EYDEAL, SOLIGEN, BEAUTY SLEEP, TRIMNASTICS and TRIMNASTICS TEA, CD - Cup D'Jour, CELLINE, and HAIR³ SYSTEM. Accordingly, an original and two copies of this notification, the text for the packaging for each brand-named is submitted for your reference.

I hereby also certify that, to the best of my knowledge, all the information submitted here is true and accurate.

Please direct all correspondence to me and feel free to call me a (973)-335 2888 if you have any question regarding this matter.

Yours sincerely,

A handwritten signature in black ink, appearing to read "P. Sewell".

Peter Sewell
Director of Product Development

Cc: Wellslife Corporation

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Tronex Company

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information@tronexcompany.com www.tronexcompany.com

#1810

TRIMNASTICS TEA

Natural Herbal Drink

TRIMNASTICS TEA is the safe and natural companion to TRIMNASTIC. It compliments the daily regime by reminding you to take a weight-reduction tea break. TRIMNASTICS and the "TEA" are made from all natural herbal ingredients.*

Ingredients: Rose, Flower Bud of Seville orange, Jasmine, Chuanxiong Rhizome, Lotus Leaf.

Dosage: Take one tea bag each time and two times a day. Pour hot water over the tea bag and let it steep for 2-4 minutes.

Packing: 60 tea bags / box

Net weight: 180g

Storage: keep in a cool and dry area.

Caution: For female users, who are pregnant or nursing, please consult your healthcare professional before taking this product. Keep out of reach of children.

Supplement Fact:

Serving size: 2 tea bags

<u>Amount per serving</u>		<u>%Daily Value</u>
Calories	17.8	**
Protein	0.21g	**
Fat	0.10g	**
Carbohydrate	4.66g	**
Fibre	1.03g	**

** Daily value (DV) not established

Other ingredients: none

A product of Wellslife Corporation

Distributed by: Tronex Pharmaceutical, Parsippany, NJ 07054, USA

BEAUTYSLEEP

All Natural Herbal Supplement

BEAUTY SLEEP helps you enjoy good sleep naturally without taking the risk of prescription drugs dependency. BEAUTY SLEEP is based on a Traditional Chinese Medicine formula, and made from all natural herbal ingredients. It is absolutely safe and effective.*

Ingredients:	Zizyphus	800mg
	Oyster shell	600mg
	Rehmanniae	600mg
	Spica Prunellae	500mg
	White Peony Root	500mg

Dosage: Take 1 packet a day with warm water one hour before bedtime.

Packing: 30 packets / box

Net weight: 90g

Storage: keep in a cool and dry area.

Caution: Do not drive or operate machineries after taking. For female users, who are pregnant or nursing, please consult your healthcare professional before taking this dietary supplement. Keep out of reach of children.

Supplement Fact

Serving size: 1 packet

<u>Amount per serving</u>		<u>%Daily Value</u>
Calories	10.7	**
Protein	0.44g	**
Fat	0.11g	**
Carbohydrate	1.9g	**
Fibre	0.53g	**

** Daily value (DV) not established

Other ingredients: none

* These statements have not been evaluated by FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

A product of Wellslife Corporation

Distributed by: Tronex Pharmaceutical, Parsippany, NJ 07054, USA