



U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

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RockStar, Inc. DBA Livingston Chocolate Company 5/23/12



Department of Health and Human Services

Public Health Service
Food and Drug Administration
New Orleans District
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Telephone: (615) 366-7801
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May 23, 2012

WARNING LETTER NO. 2012-NOL-22

UNITED PARCEL SERVICE DELIVERY SIGNATURE REQUESTED

Russell Weiner, CEO
Rockstar, Inc.
150 Shoreline Highway, Bldg E
Mill Valley, California 94941

Dear Mr. Weiner:

On January 3, 2012, an investigator with the United States Food and Drug Administration (FDA) conducted an inspection of your manufacturing facility, located at 701 N. Church Street, Livingston, Tennessee. During our inspection, our investigator collected labels of some of your products. We have reviewed the regulatory status of your Rockstar Roasted Coffee & Energy products (flavors: Premium Blended Mocha Cream & Coffee, Premium Blended Latte Cream & Coffee, and, Light Vanilla). Based on our review, these products are adulterated within the meaning of Section 402 (a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 United States Code (USC) § 342(a)(2)(C)] because they bear or contain an unsafe food additive. Specifically, they contain Ginkgo biloba leaf extract (Ginkgo), which is an unapproved food additive under Section 409 of the Act [21 USC § 348]. The regulations pertaining to the general provisions for food additives are located in Title 21, Code of Federal Regulations (CFR), Part 170. You may find the Act and FDA regulations through links at FDA's Internet home page on <http://www.fda.gov>¹.

Your Rockstar coffee products are represented for use as conventional foods, and accordingly are not dietary supplements, as defined under Section 201(ff) of the Act [21 USC § 321(ff)]. The Act excludes from the definition of a dietary supplement a product represented for use as a conventional food or as a sole item of a meal or the diet [21 USC § 321(ff)(2)(B)]. Your use of the term "energy supplement" on your label and your use of a "Supplement Facts" panel for nutrition labeling do not make your products dietary supplements, because your products are represented for use as conventional foods. Examples of factors and information which establish that the products are represented as conventional foods are as follows:

Premium Blended Mocha Cream & Coffee flavor

- The statement of identity is "Rockstar Roasted Coffee & Energy Premium Blended Mocha Cream & Coffee." Coffee is a beverage and a conventional food.
- The label states "Enjoy this fully refreshing beverage super chilled."
- The product is similar to a typical canned beverage in packaging and appearance.

Premium Blended Latte Cream & Coffee flavor

- The statement of identity is "Rockstar Roasted Coffee & Energy Premium Blended Latte Cream & Coffee." Coffee is a beverage and a conventional food.
- The label states "Enjoy this fully refreshing beverage super chilled."
- The product is similar to a typical canned beverage in packaging and appearance.

Light Vanilla flavor

- The statement of identity is "Rockstar Roasted Coffee & Energy Light Vanilla." Coffee is a beverage and a conventional food.
- The label states "Enjoy this fully refreshing beverage super chilled."
- The product is similar to a typical canned beverage in packaging and appearance.

Any substance added to a conventional food, such as your Rockstar coffee products, must be used in accordance with a food additive regulation, unless the substance is the subject of a prior sanction or is generally recognized as safe (GRAS) among qualified experts for its use in foods [21 CFR 170.30(g)]. There is no food additive regulation which authorizes the use of Ginkgo. We are not aware of any information to indicate Ginkgo is the subject of a prior sanction [see 21 CFR 181]. As explained below, we are not aware of any basis to conclude that Ginkgo is GRAS for use in conventional foods.

FDA's regulations in 21 CFR 170.30(a)-(c) describe criteria for eligibility for classification of a food ingredient as GRAS. General recognition of safety

must be based only on the views of qualified experts. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. In addition, general recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.

- Under 21 CFR 170.3(h), "[s]cientific procedures include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance." Under 21 CFR 170.30(b), "[g]eneral recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient." Section 170.30(b) further states that general recognition of safety through scientific procedures is ordinarily based upon published studies, which may be corroborated by unpublished studies and other data and information.
- Under 21 CFR 170.3(f), "[c]ommon use in food means a substantial history of consumption of a substance for food use by a significant number of consumers." Under 21 CFR 170.30(c)(1), "[g]eneral recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information." Importantly, however, the fact that a substance was added to food before 1958 does not, in itself, demonstrate that such use is safe, unless the pre-1958 use is sufficient to demonstrate to qualified experts that the substance is safe when added to food [21 CFR 170.30(a)].
- Under 21 CFR 170.3(i), "[s]afe or safety means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." The regulation provides that, in determining safety, the following factors are to be considered: (1) The probable consumption of the substance and of any substance formed in or on food because of its use; (2) the cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet; and, (3) safety factors which, in the opinion of qualified experts, are generally recognized as appropriate. Such safety factors ordinarily are established through extensive testing in animals to determine whether consumption of the ingredient produces adverse effects when consumed chronically (i.e., on a daily basis over the course of a lifetime).¹

We know of no basis for general recognition of safety for Ginkgo based either on scientific procedures or common use in food prior to January 1, 1958. In assessing the GRAS status of Ginkgo for use in conventional foods such as yours, we considered the criteria described above. FDA is not aware of data to establish the general recognition of safety of Ginkgo for use as an ingredient in conventional foods. On the contrary, reports in the scientific literature have raised safety concerns about the use of Ginkgo in conventional foods. For example, recent animal studies conducted by National Toxicology Program (NTP) showed Ginkgo to have carcinogenic activities in the animals. Therefore, the use of Ginkgo in your Rockstar coffee products does not satisfy the criteria for GRAS status under 21 CFR 170.30.

FDA is not aware of any other exemption from the food additive definition that would apply to Ginkgo for use as an ingredient in a conventional food, such as your Rockstar coffee products. Therefore, Ginkgo added to a conventional food is a food additive under Section 201(s) of the Act [21 USC § 321(s)] and is subject to the provisions of Section 409 of the Act. Under section 409, a food additive is deemed unsafe unless it is approved by FDA for its intended use prior to marketing. Ginkgo is not approved for use in any conventional food, including beverages. Therefore, your Rockstar coffee products are adulterated within the meaning of Section 402(a)(2)(C) of the Act.

You should take prompt action to correct this violation and prevent its future recurrence. Failure to do so may result in enforcement action without further notice. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products. FDA did not conduct an all-inclusive review of the above referenced products or other products you manufacture or distribute. It is the responsibility of a manufacturer to ensure that foods the firm manufactures are safe and otherwise in compliance with all applicable legal and regulatory requirements.

You should respond in writing within fifteen (15) working days from your receipt of this letter as to the specific steps you have taken to correct the violation noted above and to ensure similar violations do not occur in the future. Your response should include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for your delay and the date by which each item will be corrected and documented. If you do not believe your products are in violation of the Act, include your reasoning and any supporting information for our consideration.

Please address your reply to Karl L. Batey, Compliance Officer, at the address above. If you have questions regarding the contents of this letter, please contact Ms. Batey at (615) 366-7808.

Sincerely,

/s/

Patricia K. Schafer
District Director
New Orleans District

¹ Guidance for Industry and Other Stakeholders: Toxicological Principles for the Safety Assessment of Food Ingredients, Redbook 2000, available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/Redbook/default.htm>².

cc: Paul Storey, Director of Manufacturing
Rockstar, Inc.
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Los Angeles, California 90046

Kevin H. Garrett, General Manager
Rockstar, Inc., DBA Livingston Chocolate Company
701 N. Church Street
Livingston, Tennessee 38570-1133

Links on this page:

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