Revolt Distribution Inc. 12/8/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

December 8, 2011

VIA UPS

Jeremy E. Nickels, Owner and CEO
Revolt Distribution, Inc.
1075 Cobb International Place
Suite F
Kennesaw, GA 30152

WARNING LETTER
(12-ATL - 04)

Dear Mr. Nickels:

On July 14 – 29, 2011, the U.S. Food and Drug Administration (FDA) conducted an inspection of your distribution center located at 1075 Cobb International Place in Kennesaw, GA. We have reviewed the regulatory status of your products, "Wownie Relaxation Cookie" (also referred to in your labeling as the "Wownie Relaxation Brownie") and "Slowtivate Relaxation Drink." Your "Wownie Relaxation Cookie" and "Slowtivate Relaxation Drink" products are adulterated under section 402(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 342(a)(2)(C)] because they bear or contain an unsafe food additive. Specifically, the products contain melatonin (5-methoxy-N-acetyltryptamine, CAS Reg. No. 73-31-4), which is a neurohormone and is an unapproved food additive under section 409 of the Act [21 U.S.C. 348]. The regulations pertaining to the general provisions for food additives are located in Title 21, Code of Federal Regulations (21 CFR), Part 170. You can find copies of the Act and these regulations through links on FDA's home page at http://www.fda.gov[1].

Based on our review of your "Wownie Relaxation Cookie" and "Slowtivate Relaxation Drink" products, we conclude that these products are conventional foods. You market your "Slowtivate Relaxation Drink" product as a dietary supplement; however, it does not meet the definition of a dietary supplement because you represent it as a beverage, which is a type of conventional food.

The Act excludes from the definition of a dietary supplement any 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)]. Your use of a "Supplement Facts" panel for nutrition labeling does not make your product a dietary supplement because you represent the product as a conventional food by using the term "drink" in the statement of identity on the product label and marketing the "Slowtivate Relaxation Drink" in a single serving can similar in size, shape, and appearance to those in which single servings of beverages like soda, fruit juice, and iced tea are sold.

Your "Wownie Relaxation Cookie" product is also represented for use as a conventional food, which you appear to acknowledge with the use of a Nutrition Facts panel on this product. Additionally, the use of terms such as "cookie" or "brownie" in the product's statement of identity, the appearance and packaging of the product as a cookie (including the round cookie shape and clear plastic packaging), and the use of a combination of ingredients that includes sugar, flour, and cocoa (typical ingredients of brownies or cookies) establish that your "Wownie Relaxation Cookie" is a conventional food.

Any substance added to a conventional food, such as your "Wownie Relaxation Cookie" and "Slowtivate Relaxation Drink" 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 that authorizes the use of melatonin. We are not aware of any information to indicate that melatonin is the subject of a prior sanction [see 21 CFR Part 181]. As explained below, we are not aware of any basis to conclude that melatonin 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 melatonin based either on scientific procedures or common use in food prior to January 1, 1958. Melatonin is a neurohormone that is used for medicinal purposes, primarily as a sleep aid in the treatment of sleep-related disorders. In assessing the GRAS status of melatonin for use in conventional foods such as "Wownie Relaxation Cookie" and "Slowtivate Relaxation Drink," we considered the criteria described above. FDA is not aware of data to establish the safety of melatonin for use as an ingredient in conventional foods. On the contrary, reports in the scientific literature have raised safety concerns about the use of melatonin. Among these are concerns about effects on blood glucose homeostasis (References 1-4), and effects on the reproductive/developmental (References 5-11), cardiovascular (References 12-18), ocular (References 19-21) and neurological systems (References 22, 23). Therefore, the use of melatonin in your "Wownie Relaxation Cookie" and "Slowtivate Relaxation Drink" 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 melatonin for use as an ingredient in a conventional food, such as your brownie and drink products. Therefore, melatonin added to a conventional food is a food additive under section 201(s) of the Act and is subject to the provisions of section 409 of the Act [21 U.S.C. 348]. Under section 409, a food additive is deemed unsafe unless it is approved by FDA for its intended use prior to marketing. Melatonin is not approved for use in any food. Therefore, your

"Wownie Relaxation Cookie" and "Slowtivate Relaxation Drink" products are adulterated within the meaning of section 402(a)(2)(C) of the Act.

This letter is not intended to be an all-inclusive list of violations that may exist at your food distribution facility. It does not indicate that FDA conducted an all-inclusive review of all of the products you distribute. Your use of contract manufacturers for the adulterated products mentioned in this letter does not relieve you of your responsibility to ensure that the products you market are safe. As an own-label distributor that contracts with other firms to manufacture products that your firm releases for distribution under its own name, you have ultimate responsibility for the products that you introduce or deliver for introduction into interstate commerce. You are responsible for ensuring that your firm and products are in compliance with all requirements of the Act and pertinent FDA regulations, such as the current good manufacturing practice regulations for foods (21 CFR Part 110) and the food additive regulations (21 CFR Part 170).

You should take prompt action to correct all of the violations noted in this letter and prevent their future recurrence. Failure to do so may result in FDA taking regulatory action against your firm, such as seizure or injunction, without further notice.

We also note that the FDA has determined that your facility is subject to the registration requirement in section 415 of the Act [21 U.S.C. § 350d] and FDA's implementing regulation at 21 CFR Part 1, Subpart H. However, as of the time of our inspection, your facility was not registered with FDA. Please register your facility immediately if you still have not done so. Registration may be accomplished online at http://www.access.fda.gov[2].

Please respond to this office in writing within fifteen (15) working days from your receipt of this letter. In your response, identify the steps you have taken or will take to correct the above noted violations and prevent similar violations in the future. In your response, please include the timeframe in which the corrections will be completed and provide any documentation that will assist us in evaluating whether adequate corrective actions have been made. If you are unable to complete the corrective actions within fifteen (15) working days, identify the reason for the delay and the time within which you will complete the corrections.

Your written response should be sent to the U.S. Food and Drug Administration, Attn: Lakisha N. Morton, Compliance Officer, at the address noted in the letterhead. If you have questions, please contact Mrs. Morton at 404-253-1285.

Sincerely,
/S/
John Gridley
District Director
Atlanta Office

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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.

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