Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900
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WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

August 28, 2012 WL 41-12

Mr. Matthew A. Nicosia
President/CEO
Regeneca
1 Technology Drive
Suite C-515
Irvine, CA 92618-2339

Dear Mr. Nicosia,

This letter concerns your product “RegeneSlim”, which is labeled and/or promoted as a dietary supplement. The product labeling declares 1,3-dimethylpentylamine HCL as a dietary ingredient. This ingredient is also called, among other names, dimethylamylamine, 1,3-dimethylamylamine, DMAA or methylhexanamine, and will be referred to in the rest of this letter as dimethylamylamine.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff) [section 201(ff) of the Federal Food, Drug, and Cosmetic Act (the Act)]. Given that you have declared dimethylamylamine as a dietary ingredient in the labeling of your product, we assume you have a basis to conclude that dimethylamylamine is a “dietary ingredient” under 21 U.S.C. 321(ff)(1). Assuming that dimethylamylamine is a "dietary ingredient," it would also be a “new dietary ingredient” for which a notification is required under 21 U.S.C. 350b(a)(2) and 21 CFR 190.6.

Under 21 U.S.C. 350b, a dietary supplement that contains a new dietary ingredient (i.e., a dietary ingredient not marketed in the United States before October 15, 1994) shall be deemed adulterated under 21 U.S.C. 342(f) unless it meets one of two requirements:

1. The dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or

2. There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

To the best of FDA's knowledge, there is no information demonstrating that dimethylamylamine was lawfully marketed as a dietary ingredient in the United States before October 15, 1994, nor is there information demonstrating that this ingredient has been present in the food supply as an article used for food in a form in which the food has not been chemically altered. In the absence of such information, dimethylamylamine is subject to the notification requirement in 21 U.S.C. 350b(a)(2) and 21 CFR 190.6. Because the required notification has not been submitted, your product is adulterated under 21 U.S.C. 342(f)(1)(B) and 350b(a).

Even if the required notification had been submitted, we know of no evidence that would establish that your product is not adulterated. In the absence of a history of use or other evidence of safety establishing that dimethylamylamine, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe, "RegeneSlim" is adulterated under 21 U.S.C. 342(f)(1)(B) and 350b(a) because it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v). To the best of FDA's knowledge, there is no history of use or other evidence of safety establishing that dimethylamylamine will reasonably be expected to be safe as a dietary ingredient. In fact, dimethylamylamine narrows the blood vessels and arteries, which increases cardiovascular resistance and frequently leads to elevated blood pressure. This rise in blood pressure may increase the work of the heart such that it could precipitate a cardiovascular event, which could range from shortness of breath to tightening of the chest and/or a possible myocardial infarction (heart attack). Therefore, in the absence of a history of use or other evidence of safety establishing that dimethylamylamine is reasonably expected to be safe under the conditions recommended or suggested in the labeling of "RegeneSlim", your product is deemed to be adulterated under 21 U.S.C. 342(f).

It has come to our attention that dimethylamylamine used in products in the dietary supplement marketplace may be produced synthetically. Section 201(ff)(1) of the Act (21 U.S.C. 321(ff)(1)) defines "dietary ingredient" as a vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract or combination of any dietary ingredient from the preceding categories. Synthetically produced dimethylamylamine is not a vitamin, mineral, amino acid, herb or other botanical. To the best of FDA's knowledge, synthetically produced dimethylamylamine is not commonly used as human food or drink; therefore, it is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. Further, synthetically produced dimethylamylamine is not a concentrate, metabolite, constituent, extract or combination of a dietary ingredient. Therefore, synthetically produced dimethylamylamine is not a dietary ingredient as defined in section 201(ff)(1) of the Act.

We request that you take prompt action to correct the violations cited above, as well as any other violations associated with your product "RegeneSlim" or other products marketed by your firm that

contain dimethylamylamine. We also remind you that the new dietary ingredient notification requirement applies to all dietary supplements that contain new dietary ingredients that have not been present in the food supply as articles used for food in a form in which the food has not been chemically altered. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations

Failure to immediately cease distribution of your product "RegeneSlim" and any other products you market that contain dimethylamylamine could result in enforcement action by FDA without further notice. The Act provides for seizure of violative products and injunction against the manufacturers and distributors of violative products.

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace. Your response should also include an explanation of each step taken to assure that similar violations do not recur, as well as documentation to support your response.
Your written response should be directed to the following:

Blake Bevill
Director, Compliance Branch
U.S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2506

If you have questions regarding this letter, please contact Ms. Jessica Mu, Compliance Officer at 949-608-4477.

Sincerely,
/S/
Alonza E. Cruse
District Director

Cc: Ingeborg Small, Branch Chief
California Department of Public Health
Food and Drug Branch
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