Usp Labs 10/11/13

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
5100 Paint Branch
Parkway
College Park, MD 20740

October 11, 2013

WARNING LETTER

Via Electronic Mail

Mr. Jacob Geissler
CEO and Co-Owner
USP Labs, LLC
10761 King William Dr.
Dallas, TX 75220-2445

Re: Case # 413065

Dear Mr. Geissler:

This letter concerns your products Oxy Elite Pro and VERSA-1 that are labeled and/or promoted as dietary supplements. The labeling for these products declares aegeline, also referred to as N-[2-hydroxy-2(4-methoxyphenyl) ethyl]-3-phenyl-2-propenamide, as a dietary ingredient.

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 declared aegeline, also referred to as N-[2-hydroxy-2(4-methoxyphenyl) ethyl]-3-phenyl-2-propenamide, as a dietary ingredient in the labeling of your products, we assume you have a basis to conclude that aegeline is a “dietary ingredient” under 21 U.S.C. 321(ff)(1). Assuming that aegeline 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.

FDA is not aware of any information demonstrating that aegeline was lawfully marketed as a dietary ingredient in the United States before October 15, 1994, nor is FDA aware of any 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, aegeline 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 products are adulterated under 21 U.S.C. 342(f)(1)(B) and 350b(a).

In the absence of a history of use or other evidence of safety establishing that aegeline, when used under the conditions recommended or suggested in the labeling of your products, will reasonably be expected to be safe, Oxy Elite Pro and VERSA-1 are adulterated under 21 U.S.C. 342(f)(1)(B) and 350b(a) because they contain 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). FDA is aware of no history of use or other evidence of safety establishing that aegeline will reasonably be expected to be safe when used under the conditions recommended or suggested in the labeling of OxyElitePro and Versa-1.

The importance of establishing that products containing aegeline will reasonably be expected to be safe when used under the conditions recommended or suggested in the labeling of your product is particularly important in the present setting where public health officials in Hawaii and elsewhere within the United States are actively investigating a number of severe illnesses characterized by hepatotoxicity where affected patients report using a product labeled as Oxy Elite Pro. Several findings suggest a causal connection may exist between ingestion of a product labeled as Oxy Elite Pro and the illnesses reported in Hawaii. First, in a review of twenty (20) medical records submitted to FDA by the Hawaii Department of Health, the records indicated that fourteen (14) patients (70%) had ingested a product labeled as Oxy

Elite Pro prior to becoming ill. There were no other consistent commonalities among the fourteen (14) patients other than exposure to Oxy Elite Pro. Importantly, eight (8) patients reported Oxy Elite Pro as the sole dietary supplement they took prior to becoming ill, and most of these patients had been entirely healthy before they became ill. Second, upon discontinuing Oxy Elite Pro following onset of illness, most patients recovered from their illness, implying Oxy Elite Pro was the cause of the illness. Unfortunately, several patients sustained injuries to the liver that required transplantation, and one patient died before transplantation could be undertaken. And finally, rigorous clinical protocols were followed in the care of the patients to exclude and/or rule out known causes of liver disease (e.g., viral causes of hepatitis, autoimmune conditions, hemochromatosis, Wilson's disease, excess alcohol or acetaminophen ingestion, and alpha-1-antityrpsin deficiency). The absence of these causes of liver disease increases the likelihood that Oxy Elite Pro played a hepatotoxic role in these patients. Therefore, in the absence of a history of use or other evidence of safety establishing that aegeline is reasonably expected to be safe under the conditions recommended or suggested in the labeling of Oxy Elite Pro and VERSA-1, your products are deemed to be adulterated under 21 U.S.C. 342(f).

We request that you take prompt action to correct these and any other violations associated with Oxy Elite Pro and VERSA-1 and any other products marketed by your firm that contain aegeline. We again remind you that the notification requirement for a new dietary ingredient applies to any dietary supplement that contains a new dietary ingredient that has not been present in the food supply as articles used for food in a form in which the food has not been chemically altered.

Failure to immediately cease distribution of all products containing aegeline may result in enforcement action by FDA without further notice. The Act provides various tools to remedy adulterated or misbranded foods, including administrative detention order(s) and seizure(s) against adulterated or misbranded food products in the marketplace, injunction against the manufacturers and distributors from further violating the Act, and criminal sanctions against persons responsible for causing violations of the Act.

We request that you advise us in writing, within fifteen (15) working days of receiving 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 adulterated product currently in the marketplace. Your response should also include an explanation of each step taken to assure that similar and repeated violations do not recur, as well as documentation to support your response. Please submit your response to Mr. Quyen Tien at the above letterhead address. Please provide a copy of your response to Mr. Reynaldo R. Rodriguez, Jr., Dallas District Director, U.S. Food and Drug Administration, 4040 North Central Expressway, Suite 300, Dallas, Texas 75204. If you have any questions, please contact Mr. Tien at 215-717-3705.

Sincerely,
/S/
William A. Correll Jr
Acting Director
Office of Compliance

Center for Food Safety
and Applied Nutrition

cc:

Mr. Jonathan V. Doyle
President

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