
**Frost
Brown Todd** LLC
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May 24, 2004

Steven J. Rabe
Compliance Officer
Food & Drug Administration
Cincinnati District Office – Central Region
6751 Steger Drive
Cincinnati, Ohio 45237

Re: Warning Letter of May 3, 2004

Dear Mr. Rabe:

This letter is on behalf of our client, Peak Performance Foods, LLC (“Peak Performance”) and, as indicated above, is in response to the warning letter dated May 3, 2004, concerning Peak Performance’s PRO BITES® products.

Before we respond to the specific concerns outlined in Ms. Heppe’s warning letter, it is important that we make a couple of observations on behalf of our client. Peak Performance is a small and relatively new company, and it is clear that the advice it received with respect to how to label the PRO BITES® products was incomplete and inadequate in general and, in several instances, incorrect. It is important to note, though, that this is not a case of a manufacturer intentionally choosing to disregard relevant regulations. As a board-certified surgeon with many years of experience caring for patients with physical problems directly related to improper diets, Dr. Snodgrass, the CEO of Peak Performance, is interested in trying to help people by providing better and more healthful snacking alternatives. He simply was not aware that the studies with which he is familiar that link higher protein consumption with better weight control do not, under the relevant regulations, by themselves enable the making of claims like those on the PRO BITES® labels. While ignorance of the law is no excuse, Dr. Snodgrass and the other employees of Peak Performance wish to assure you that they will take the steps necessary to correct current problems and to guard against future issues with the company’s labels and claims.

Peak Performance’s responses to the matters noted in the warning letter are as follows:

1. **“Fights Obesity” Claim.** Peak Performance acknowledges your concerns with respect to this claim and will delete it from its packaging.
2. **“Low Carb” Claim.** Peak Performance acknowledges the FDA’s position on this issue and will delete the “low carb” claim from its packaging. Given, however, the wide variety of circumstances under which such claims are now being made in the marketplace, Peak Performance joins with other interested parties who have encouraged the FDA to authorize low carbohydrate claims and to provide guidance on when such claims might properly be made.
3. **“Low Fat” Claim.** Peak Performance will delete this claim from the labeling for these products unless and until it develops products that meet the regulatory requirements for making a “low fat” claim.
4. **Serving Size.** The serving size problem will be corrected. Peak Performance intends to package the PRO BITES® product in the future in a one-ounce single-serving container and will base the nutrition information disclosed on the total amount of product in the package.

No PRO BITES® products have been produced since the FDA’s concerns with the labeling first came to the Company’s attention, and there will be no further production until new packaging is available. Design work on the new labels implementing the above commitments is in process and should be completed within the next several weeks. The Company would be happy to provide you with a copy of those new designs when they become available, if that would be helpful.

In closing, I would like to once again express on behalf of Peak Performance its dismay that compliance problems existed with respect to the labeling of its PRO BITES® products, and reaffirm its commitment to ensure that the products comply fully in the future. If you wish to discuss any of the points made in this letter, please contact the undersigned.

Very truly yours,

FROST BROWN TODD LLC

By: /s/ Steven J. Ellcessor
Steven J. Ellcessor