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SEP 15 2005

Nancy L. Schnell
Deputy General Counsel
Marketing and Regulatory
Unilever United States, Inc.
700 Sylvan Avenue
Englewood Cliffs, New Jersey 07632

Dear Ms. Schnell:

First, I would like to thank you for the information and comments presented in your December 1, 2004, letter regarding the claim "Net Atkins Count." Information that we receive from the regulated industry is often very helpful in our enforcement of the Federal Food, Drug, and Cosmetic Act.

As you are aware, the Food and Drug Administration's (FDA) Working Group on Obesity (OWG) published a report on March 12, 2004. One of the recommendations in the OWG report is for FDA to publish a proposed rule to define terms for nutrient content claims related to the carbohydrate content of foods and provide guidance for the use of the term "net" in relation to the carbohydrate content of foods. FDA's Office of Nutritional Products, Labeling and Dietary Supplements is working to address the OWG recommendations. Publication of regulations governing carbohydrate nutrient content claims will provide reliable information in food labeling to assist consumers in making informed dietary choices consistent with dietary guidelines, and bring uniformity back to the marketplace.

As you know, firms are not prohibited from declaring other quantitative information outside of the nutrition label provided the additional information is not false or misleading. We recognize that there are various types of quantitative "net" claims in the marketplace. At this time, however, we are not generally objecting to additional quantitative "net" carbohydrate-type statements that are truthful and not misleading; for example, where the "net" terms are sufficiently explained on the label so that the consumer understands the meaning of the use of such terms.

Please be assured that your letter has been noted and copies will be added to Docket 2004P-0298. We would appreciate your submission to this docket of any available consumer data that you may be aware of to substantiate your concerns regarding the misleading nature of the terms in question.

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We would also appreciate receiving any available consumer data or information to substantiate your belief that the claim “Net Atkins Count” is in fact misleading to consumers.

Thank you again for your input.

Sincerely yours,

A handwritten signature in black ink that reads "Michael M. Landa". The signature is written in a cursive style with a large, stylized initial "M".

Michael M. Landa
Deputy Director
for Regulatory Affairs
Center for Food Safety
and Applied Nutrition



Nancy L. Schnell
Deputy General Counsel - Marketing and Regulatory

December 1, 2004

VIA OVERNIGHT MAIL

Michael M. Landa
Deputy Director for Regulatory Affairs
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Department of Health and Human Services
5100 Paint Branch Parkway, Building CPK1
College Park, Maryland 20740-3835

RE: Use of the term "Net Atkins Count™" on Food Labels

Dear Mr. Landa:

This letter provides comments on the food labeling claim "Net Atkins Count™" and requests that FDA act promptly to prevent this claim from being used. This supplements our letter to FDA of June 29, 2004, in which we provided comments on the term "net carbohydrates." This also supplements our petition for nutrient content claims for carbohydrates (Docket No. 2004P-0298).

Summary

Atkins Nutritionals, Inc. ("Atkins") has reportedly begun to use a new labeling claim to describe the carbohydrate levels in food products that it markets. This claim is "Net Atkins Count™," a trademarked phrase that is based on a patent-pending scientific methodology. It cannot be used by food marketers other than Atkins (or those authorized by Atkins). Thus, in effect, it is a new, proprietary definition of a nutrient that uses a "black-box" scientific methodology to create a number with an unknown meaning.

When an Atkins food bears the claim "Net Atkins Count™," it will be uniquely labeled because both the terminology and the methodology on which the claim is based are proprietary. Other similar, non-Atkins foods will need to be labeled differently – they will need to be labeled with, for example, "net carbohydrates" based on a different scientific methodology because they are not authorized to use "Net Atkins Count™." Thus, the Atkins claim *mandates* different labeling for products that are not meaningfully

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different. Indeed, consumers could interpret Atkins-labeled products as better for use in a weight loss diet than other products, even when this is not the case. This is misleading. In fact, the proprietary nature of the Atkins claim causes it to be *inherently* misleading because it cannot be made non-misleading by a disclaimer or other qualifying language.

The Atkins claim will also be misleading to consumers who do not understand what the word "Atkins" means or who otherwise misinterpret the claim. For example, consumers might misinterpret the claim as referring to calories, fat, or other nutrients that should be controlled as part of a weight loss diet.

Importantly, Atkins' effort to define and regulate its own, proprietary nutrient definition using a black-box scientific methodology undermines FDA's use of consistent nutrient definitions on which food labeling claims are based. This, of course, must be discouraged.

For these reasons, we urge FDA promptly to prevent the use of "Net Atkins Count™" and clarify that it is inappropriate to use such proprietary claims on food labeling.

A detailed discussion of these points follows.

Discussion

On October 6, 2004, the *Wall Street Journal* reported that Atkins Nutritionals, Inc. ("Atkins") had begun to use a new labeling term to describe the carbohydrate levels in food products that it markets. This new term is "Net Atkins Count™." The company's website explains this term as follows:

[Atkins has developed a] "unique scientific method ... to substantiate the low glycemic impact of Atkins products and confirm the accuracy of Atkins net carb labeling claims. Net carbs are those carbohydrates that have a significant impact on blood-sugar levels, and limiting net carbs is the most critical factor for people who wish to successfully follow the Atkins Nutritional Approach™. To date, food manufacturers have relied on a simple subtraction method to approximate net carbs, subtracting carbs that have a negligible impact on blood sugar, specifically fiber, glycerine and sugar alcohols, from total carbs. Atkins too utilized this subtraction method, and Atkins labels accurately reflected the net carb count of Atkins products based on state-of-the-art science at the time of manufacture. But now, Atkins has developed a patent-pending clinical method that actually measures the glycemic impact of specific products. As a result, Atkins label claims are validated by actual clinical testing, as well as the subtraction method. We have begun to use this new method to validate the number of net carbs in Atkins food products so

that you can be assured that our product labeling is supported by the best scientific methods available. Going forward, on its next generation of labels, Atkins will use the term Net Atkins Count™ to express this clinically validated number for its products and to distinguish it from terms such as net carbs used previously.”¹

As Atkins clearly explains, the claim “Net Atkins Count™” is proprietary. It is a trademark that conveys information derived from tests conducted under a “patent-pending clinical method.” In effect, it is a new, proprietary definition of a nutrient that uses a black-box scientific methodology to create a number with an unknown meaning.

Because it is a trademark based on a patent-pending method, this claim may not be used by food marketers other than Atkins (or those licensed by Atkins). As a result, the information conveyed by this claim will invariably be different from information about “net carbohydrates” that is provided by other manufacturers.

It is fundamental to the usefulness of food labeling claims that they are based on a common set of scientific criteria to which all marketers have equal access. Indeed, when FDA implemented the Nutrition Labeling and Education Act of 1990 (NLEA), it recognized that one of the key goals of the Act was to eliminate consumer confusion by establishing definitions for nutrition information that would be consistent for the industry as a whole.² If FDA permits the claim “Net Atkins Count™” to be disseminated on food labels, then other manufacturers will be justified in developing their own proprietary approaches to nutrient declaration, resulting in claims such as “*net [NAME OF COMPANY] fat*,” “*net [NAME OF COMPANY] saturated fat*,” or “*[NAME OF COMPANY] glycemic index*.” Obviously, these types of claims would be inconsistent with the goal of the NLEA.

Importantly, the proprietary nature of the claim “Net Atkins Count™” causes it to be inherently misleading. To see why this is so, consider the example of a manufacturer who markets a food that is formulated identically to an Atkins product. The non-Atkins food may be labeled with “net carbohydrate” information, but this information will differ from the “Net Atkins Count™” on the Atkins product (because both the terminology and the methodology used to derive the claim are different). As this example shows, there will always be an apparent difference between Atkins products and other products, even when no difference exists. Because it is proprietary, the Atkins claim *mandates* different labeling for products that are not meaningfully different. Indeed, consumers could interpret the Atkins-labeled products as better for use in a weight loss diet than other products, even when this is not the case.

¹ <http://atkins.com/Archive/2004/10/5-366283.html> (accessed November 22, 2004).

² See e.g., 58 Fed. Reg. 2302 (January 6, 1993).

As a result, the proprietary nature of the Atkins claim causes it to be *inherently* misleading because it cannot be made non-misleading by use of a disclaimer or other qualifying language.³ Therefore, it may not legally be used on food labeling. In addition, there are several other reasons why this claim would be misleading if used on food labels. For example:

- The word "Atkins" may be unfamiliar to some consumers who may interpret the claim incorrectly as additional, FDA-authorized nutrition information. These consumers may be confused about how to interpret the Nutrition Facts box in light of this claim and, as a result, disregard nutrition information that may be important to them.
- The word "Atkins" may suggest to consumers that the product is for use in a weight loss diet. Some consumers could interpret the claim incorrectly as referring to calories, fat, or other nutrients that should be controlled as part of a weight loss diet. Some consumers could also interpret the claim as meaning that the labeled food will by itself facilitate weight loss.
- It is unclear whether the "patent-pending clinical method" to measure the glycemic impact of specific products for purposes of deriving the "Net Atkins Count™" has been validated. Atkins must ensure the validity of the method with respect to applicability, specificity, sensitivity, accuracy, precision, and detectability.⁴

Finally, it is important to note that, with its claim, Atkins is establishing itself as a "mini-FDA," regulating the meaning of its new, proprietary nutrient definition using a black-box scientific methodology. (Moreover, to the extent that Atkins licenses its claim, it would be doing this for profit.) This behavior (and imitative behavior by other marketers) undermines FDA's use of consistent nutrient definitions on which food labeling claims are based and encourages the increased use of misleading claims in the marketplace. We urge FDA to act to prevent this result.

Conclusion

For the reasons discussed above, the claim "Net Atkins Count™" is misleading when used on food labels, in violation of §403(a) of the Federal Food, Drug, and Cosmetic Act. We respectfully request that FDA take prompt action to prevent the use of this claim. We

³ The Atkins claim is misleading because it is a new, proprietary definition for a nutrient. In this regard, it is different than third-party-authorized label statements such as the American Heart Association's (AHA) Food Certification ("Heart Check") Program. The AHA program merely identifies foods that have certain characteristics based on FDA-established nutrient definitions to which all marketers have equal access.

⁴ See 58 Fed. Reg. 2302 (January 6, 1993) (comment 21).

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further request that, when FDA issues guidance on "net carbohydrate" claims, it clarify that this and similar proprietary claims may not be used.

Thank you for considering our comments on this important issue.

Sincerely,



Nancy L. Schnell
Deputy General Counsel –
Marketing and Regulatory

cc: Barbara O. Schneeman, Ph.D.
Kathleen Ellwood, Ph.D.
Office of Nutritional Products, Labeling
and Dietary Supplements (HFS-800)

Joseph R. Baca
Office of Compliance (HFS-600)

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