



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

975 76 JUL 28 10:00

JUN 30 2004

Mr. Mark W. Rollinson  
President  
Kendy USA LLC  
704 Juniper Drive  
Palatine, Illinois 60074

Dear Mr. Rollinson:

This is in response to your letter to the Food and Drug Administration (FDA) dated April 28, 2004. In your letter, you stated that you disagreed with FDA's view that the claim "[m]ay help maintain normal blood cholesterol levels" is a disease claim as we asserted in our letter to you dated April 6, 2004. You also stated that you intended to revise the claim about BIOPLUS+ restoring intestinal flora to comply with the requirements of the Federal Food, Drug, and Cosmetic Act (the Act).

In your letter, you stated that "By definition, we feel the words 'help maintain normal' clearly imply that the use of probiotics is only one factor in maintaining (i.e., stabilizing without change) normal (i.e. within normal range) blood cholesterol levels" and that there is no implied claim relating to the reduction of high cholesterol levels. As we have previously stated, in the preamble to the final rule, FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid making a cholesterol maintenance claim into an implied claim, a cholesterol maintenance claim would have to explicitly disclaim the implied ability of the product to prevent the development of elevated cholesterol levels or to reduce an elevated cholesterol. Therefore, an appropriate structure/function claim about maintaining cholesterol should explicitly state that the cholesterol levels that are the subject of the claim are "already within the normal range." Your April 28 letter does not change our view. We do not believe that the meaning of "help maintain normal" limits the meaning of the claim to only effects on already normal cholesterol levels, but rather includes effects on preventing elevations of cholesterol levels outside of the normal range and reductions of elevated cholesterol into the normal range. For this reason, we are not persuaded that the conclusion expressed in our April 6, 2004 letter is incorrect and we stand by our original determination that the claim proposed in your original submission is a disease claim that subjects your product to regulation under the drug provisions of the Act.

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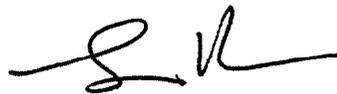
Page 2 - Mr. Mark W. Rollison

You also proposed to revise the claim "Restores intestinal flora after antibiotic treatment and intestinal infection" to "may restore and maintain normal gastro-intestinal micro flora after antibiotic treatment." In the preamble to the January 6, 2000 final rule, we specifically discussed the claim you propose to make and stated that such a claim, in the context of maintaining or restoring normal intestinal microflora in persons using antibiotics constituted an implied disease claim (see 65 FR 1000 at 1029). We stated that while such claims do not explicitly refer to a disease, "there is an implicit claim that use of the dietary supplement while taking antibiotics will prevent or mitigate a disease," namely the overgrowth in the gut of pathogenic organisms that can be a result of the antibiotic suppressing the normal intestinal flora that typically prevent infection in the intestinal tract of otherwise healthy persons. Therefore, the revised claim you propose to use is a disease claim that subjects your product to regulation under the drug provisions of the Act.

Finally, we wish to comment on your stated understanding regarding the submission of the notification pursuant to 21 U.S.C. 343(a)(6) and 21 CFR 101.93(a). The Act requires that the "manufacturer notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made." See 21 U.S.C 343(r)(6), concluding sentence. Nothing in the statute nor in the agency's regulations mandates that FDA review and respond to this notification within 30 days of submission. Moreover, nothing in the statute or regulations, implicitly or explicitly, can be interpreted to mean that if FDA does not comment on a notification that the agency's silence constitutes an approval by the agency of the product or its claims. While FDA makes an effort to comment, if it intends to, on notifications in a timely manner, the fact that the agency does not comment or is unable to comment within a certain time frame in no way impacts on whether a particular claim is a claim permitted for use in dietary supplement labeling under 21 U.S.C. 343(r)(6).

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Page 3 - Mr. Mark W. Rollison

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Chicago District Office, Compliance Branch, HFR-MW140

Kendy USA LLC

28 April, 2004

RECEIVED  
MAY 12 2004  
BY:

Susan J. Walker  
Director, Division of Dietary Supplement Programs  
Food and Drug Administration  
5100 Paint Branch Parkway, HFS-810  
College Park, MD 20740-3835

**RE: Your letter dated April 6 2004 pertaining to Kendy USA LLC –  
Notification pursuant to Section 6 of DSHEA and 21 CFR 101.23**

Dear Ms. Walker:

It is our intention to modify the claim on our packaging referencing human gastro-intestinal micro flora so that it reads as follows;

*“(may) restore and maintain normal gastro-intestinal micro flora after antibiotic treatment.”*

Therefore any and all reference to intestinal infections will be removed. We believe that a large preponderance of clinical studies carried out on probiotic supplements support the claim as worded above. Indeed doctors in the USA commonly and regularly advise their patients to go on a course of probiotics after completing prescribed antibiotic treatment for this specific reason.

Given that claims relating to constipation, bloating, diarrhea & flatulence are, in general, classed as being Structure/Function claims we believe that our wording as shown below is justifiable and supported by the preponderance of clinical studies.

*“(may) prevent constipation, bloating, diarrhea & flatulence.”*

With regard to claims relating to cholesterol levels. The wording on our packaging is currently *“(may) help maintain normal blood cholesterol levels”*. By definition, we feel the words “help maintain normal” clearly imply that the use of probiotics is only one factor in maintaining (i.e. stabilizing without change) normal (i.e. within normal range) blood cholesterol levels. We do not believe that there is any specific or implied claim relating to the reduction of high cholesterol levels. There is also no reference to coronary heart disease.

Kendy USA LLC  
“Your partner is business”

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April 28, 2004  
Page 2

We also include on our packaging the standard required disclaimer that  
*"These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease"*

Our attorney informed us that the FDA had 30 days from the date of submission of the packaging text in which to register any comments, required changes etc. Your response to our packaging text was received in excess of 90 days after submission and, as we are getting very close to our product launch deadline, I would appreciate your comments on both this issue and the text details previously mentioned as promptly as possible.

Many thanks in anticipation of your assistance.

Sincerely,



Mark W. Rollinson  
President  
Kendy USA LLC  
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Palatine, IL 60074  
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