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AUG - 2 2001

Mr. Lawrence Tabak  
President  
Tabak's Health Products  
3198-G Airport Loop Drive  
Costa Mesa, California 92626

Dear Mr. Tabak:

This is in response to your letter to the Food and Drug Administration (FDA) dated June 18, 2001 responding to our letter to you dated June 4, 2001 concerning claims that you were making for certain of your products. In our June 18, 2001, we stated that the claims "...maintain healthy blood sugar levels," "...prevention of coronary heart disease," and "relieve pain, stiffness, inflammation and tenderness" would not be appropriate structure/function claims under 21 U.S.C. 343(r)(6).

In the preamble to the January 6, 2000 final rule (see 65 FR 1000), FDA stated that health maintenance claims that do not imply disease treatment or prevention would be acceptable structure function claims. We stated that if the health maintenance claim did not use terms that are so closely identified with a specific disease or that so clearly referred to a particular at-risk population, we believed that such a claim could be a structure/function claim under 21 U.S.C. 343(r)(6) (see discussion at 65 FR 1018). You stated in your letter that you believe that the claim "...maintain healthy blood sugar levels" is an appropriate structure/function claim that does not imply disease treatment, prevention, or mitigation because you had qualified it in a manner analogous to the manner that we described as an appropriate structure or function claim in the January 6, 2000 final. Furthermore, you stated that you had explicitly included a statement that the product was "not intended to have an effect on abnormal blood glucose." We have reviewed your original submission and we agree in part and disagree in part.

As you know, we stated in the preamble to the final rule that a claim such as "use as part of your diet to help maintain a healthy blood sugar level" would be an acceptable structure/function claim. Such a qualification of your claim is included in your web site material about the product BetiPlus. Consequently, the claims for the product made on the web site material you submitted appear to be appropriate structure or function claims.

However, we disagree that the claims about maintaining healthy blood glucose levels made in print promotional material you submitted are similarly qualified; in fact, there is no

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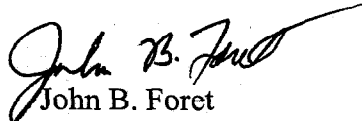
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mention in that information about the product being intended to be used as part of a healthy diet. While that printed material includes a disclaimer (i.e., not intended to have an effect on abnormal blood glucose), the mere inclusion of a perfunctory disclaimer is not enough to make the claims appropriate structure or function claims because it does not say what, if not ~~to correct abnormal glucose, the product is intended for other than~~ "for maintaining healthy blood glucose." As such, the claim is simply a claim that the product is intended to maintain normal (or healthy) blood glucose levels, which is an implied disease claim. This conclusion is based on the fact that a claim about external intervention to affect blood glucose levels is implicitly a claim to correct a defect in blood glucose levels because it is not necessary to improve, modify, or otherwise affect blood glucose unless it is impaired. The mere presence of the disclaimer is not enough, in our opinion, to correct this implicit disease claim.

You also state that your claim for the product Mega JointWellness (i.e., relieve pain, stiffness, inflammation and tenderness") is not a disease claim because that claim, while a part of the labeling of Mega JointWellness, is actually a claim for a different product. We disagree. The claim states that "It [Mega JointWellness] can and should be combined with Arthritis-Ease, the homeopathic remedy to relieve pain, stiffness, inflammation and tenderness in joints." This claim explicitly represents Mega JointWellness as an adjunct to a product intended for use as a disease therapy and it is, therefore, evidence that this product is also intended to treat the same disease, namely arthritis (see 21 CFR 101.93(g)(2)(vii)).

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

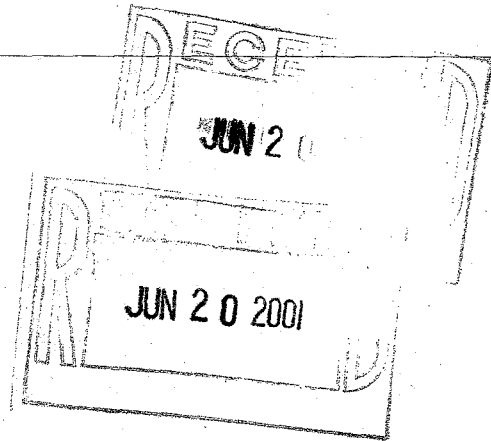
Copies:

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, Los Angeles District Office, Compliance Branch, HFR-PA240

76480

June 18, 2001

John B. Foret  
Food and Drug Administration  
Department of Health & Human Services  
200 C Street SW  
Washington, DC 20204



Dear Mr. Foret,

This is in response to your letter to Tabak's Health Products dated June 4, 2001.

In reference to your comments about our claims, here are our answers:

**BetiPlus**

"...maintain healthy blood sugar levels..."

In your letter to our company dated October 24, 2000 (copy enclosed), you stated that if we made it clear and unambiguous that our product is not intended to have an effect on abnormal blood glucose then a statement of nutritional support for maintaining healthy blood glucose, which is already healthy, could be acceptable. Insofar as that is concerned, we did as you said and made it clear and unambiguous in our literature that our product is not intended to have an effect on abnormal blood glucose. We kindly ask for you to refer back to our submission made on December 20, 2000, where you will see this has been done.

**Heartshield**

"...prevention of coronary heart disease..."

This statement will be removed from our literature.

**Mega JointWellness**

"...relieve pain, stiffness, inflammation and tenderness..."

June 18, 2001

The above statement, in our literature, refers to a homeopathic medicine "Arthritis-Ease", which is not a nutritional supplement. This statement clearly and unambiguously does not refer in any way to our Mega JointWellness product.

**Slender Blend**

We will no longer refer to this product as a dietary supplement. From now on, we will only refer to it as a meal replacement drink.

Please, would you be kind enough to acknowledge receipt of this correspondence.

Sincerely,



Lawrence Tabak  
President

P.S. The above referenced changes will be incorporated at our earliest convenience, as soon as we re-print the literature.



OCT 24 2000

Mr. Lawrence Tabak  
President  
Tabak's Health Products  
3198-G Airport Loop Drive  
Costa Mesa, California 92626

Dear Mr. Tabak:

This is in response to your letter to the Food and Drug Administration (FDA) dated October 10, 2000. In your letter, you asked us to explain the basis for our position, stated in a letter to you dated September 20, 2000, that the statement "helps maintain normal blood sugar levels" is not a claim that may be made for dietary supplements pursuant to 21 U.S.C. 343(r)(6).

In our May 22, 2000 letter, we stated that the claim "...help maintain normal blood sugar levels" would not be an appropriate structure/function claim under 21 U.S.C. 343(r)(6). In the preamble to the January 6, 2000 final rule (see 65 FR 1000), FDA stated that health maintenance claims that do not imply disease treatment or prevention would be acceptable structure function claims. We stated that if the health maintenance claim did not use terms that are so closely identified with a specific disease or that so clearly referred to a particular at-risk population, we believed that such a claim could be a structure/function claim under 21 U.S.C. 343(r)(6) (see discussion at 65 FR 1018).

You stated in your letter that you believe that the claim "...help maintain normal blood sugar levels" is an appropriate structure/function claim that does not imply disease treatment, prevention, or mitigation because we stated in the preamble to the final rule that a claim such as "use as part of your diet to help maintain a healthy blood sugar level" would be an acceptable structure/function claim. We disagree. We believe that any claim that a product is intended to maintain normal blood glucose levels is an implied disease claim. This conclusion is based on the fact that a claim about external intervention to affect blood glucose levels is implicitly a claim to correct a defect in blood glucose levels because it is not necessary to improve, modify, or otherwise affect blood glucose unless it is impaired.

However, a claim that a product is important or plays a role in the maintenance or regulation of blood glucose that is already normal or within normal limits could be an appropriate structure/function claim, depending on the context. As we discussed in the preamble to the final rule, the context in which a particular claim is made is important in determining whether

a claim may be a disease claim or a structure/function claim. Consequently, if the context of a claim about a product intended to affect blood glucose clearly and unambiguously makes clear that the product is not intended to have an affect on abnormal blood glucose (for example, the claim in the preamble of the January 6, 2000 final rule which you cited in your letter), then such a claim may be an acceptable structure/function claims under 21 U.S.C. 343(r)(6). But, the claim you are making for your product contains no such context and, consequently, is not an acceptable structure/function claim under 21 U.S.C. 343(r)(6).

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Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement

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