



DEC 6 2004

Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, Maryland 20740

Mr. Bo Zhu  
President  
Syntech (SSPF) International, Inc.  
310 Paseo Tesoro  
Walnut, CA 91789

Dear Mr. Zhu:

This letter is in response to your submission to the Food and Drug Administration (FDA), dated September 17, 2004, for a new dietary ingredient made pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 190.6. Your letter notified FDA of your intent to market "Betaphrine", a substance that you assert is a new dietary ingredient.

The term "dietary supplement" is defined in the Act, as amended by the Dietary Supplement Health and Education Act of 1994, as a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients (21 U.S.C. 321(ff)(1)). Moreover, to be a dietary supplement, a product must be intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or comply with 21 U.S.C. 350(c)(1)(B)(ii), must not be represented as conventional food or as a sole item of a meal or the diet, and must be labeled as a dietary supplement (21 U.S.C. 321(ff)(2)). The definition excludes an article that is authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such authorization, marketed as a dietary supplement or as a food (21 U.S.C. 321(ff)(3)(B)).

FDA has carefully considered the information in your submission, and we have concluded that "Betaphrine" is not a dietary ingredient under 21 U.S.C. 321(ff)(1). "Betaphrine" is not a vitamin, mineral, herb or other botanical, an amino acid, dietary substance for use by man to supplement the diet, or a concentrate, metabolite, constituent, extract or combination of any ingredient described above. Rather, "Betaphrine" appears to be a chemically synthesized substance. While it may be synthesized using one or more precursors that are themselves dietary ingredients, a substance such as "Betaphrine" that is chemically synthesized using such substances as starting material is not itself a substance defined in 21 U.S.C. 321(ff)(1) because it is not a concentrate, metabolite, constituent, extract, or combination of any ingredient described in this section. Therefore, "Betaphrine" is not a dietary ingredient.

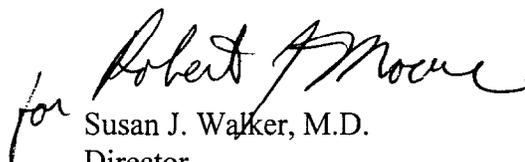
Your submission states that "Betaphrine" is intended for use by consumers "[F]or the purpose of supporting the maintenance of normal weight." Inasmuch as such a product is clearly not a dietary ingredient, as discussed above, or a conventional food, this product is a "drug" under 21 U.S.C. 321(g)(1)(C) because it is intended to affect the structure or function of the body. Moreover, your product also appears to be a "new drug," as defined in 21 U.S.C. 321(p), which requires FDA approval under 21 U.S.C. 355(a) prior to marketing.

In sum, the ingredient for which you have submitted a new dietary ingredient notification is not a dietary ingredient under the Federal Food, Drug, and Cosmetic Act. Moreover, the product to which you refer in your submission appears to be a drug under the Act and thus subject to the regulatory requirements of drugs. Introduction of a new drug into interstate commerce is prohibited under 21 U.S.C. 355(a) prior to approval of an application under subsections (b) or (j) of 21 U.S.C. 355. In addition, because the Agency concluded that "Betaphrine" is not a dietary ingredient, FDA did not review evidence of safety information that you submitted for this substance.

Your notification will be kept confidential for 90 days after the filing date of September 24, 2004. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Commercial and confidential information in the notification will not be made available to the public. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Linda Pellicore, Ph.D. at (301) 436-2375.

Sincerely yours,

for Robert F. Moore

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