DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

DEC - 1 2005

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Life Enhancement Products, Inc.
P. O. Box 751390
Petaluma, CA 94975-1390

Re: "Starters' Traditional Chinese Ephedra Herbal Tea"

Dear Sir or Madam:

The Food and Drug Administration (FDA) has reviewed the label of your "Starters' Traditional Chinese Ephedra Herbal Tea" and has analyzed samples of the product. Based on this review and analysis, FDA has concluded that "Starters' Traditional Chinese Ephedra Herbal Tea" is adulterated under section 402(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 342(a)(2)(C)), in that it bears or contains an unsafe food additive, Ma Huang, also known as Ephedra. FDA has also concluded that this product is misbranded under section 403(q)(1) of the Act (21 U.S.C. 343(q)(1)) in that the nutrition information on the product label fails to meet the requirements of Title 21, Code of Federal Regulations, Section 101.9 (21 CFR 101.9).

Any substance intentionally added to a conventional food, such as a beverage product, must be used in accordance with a food additive regulation approving the substance for that use, unless the substance is generally recognized as safe (GRAS) among experts qualified by scientific training and experience to evaluate its safety ("qualified experts") under the conditions of its intended use, or is otherwise exempt from the food additive definition in section 201(s) of the Act (21 U.S.C. 321(s)).

Ma Huang is listed as an ingredient on your product label. Ma Huang is the Chinese name for the ephedra plant. Ephedra species produce ephedrine alkaloids, the active constituents thought to be responsible for the reported pharmacological effects associated with medicinal and dietary supplement use of ephedra.

FDA's regulations in 21 CFR Part 170 describe criteria for eligibility for classification of a food ingredient as GRAS. Under 21 CFR 170.30(a), general recognition of safety must be based only on the views of qualified experts. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.

FDA's regulations in 21 CFR Part 170 define "common use in food" and establish criteria for eligibility for classification as GRAS through experience based on common use in food. Under 21 CFR 170.3(f), "[c]ommon use in food means a substantial history of consumption of a substance for food use by a significant number of consumers." Under 21 CFR 170.30(c)(1), "[g]eneral recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information." Importantly, however, the fact that a substance was added to food before 1958 does not, in itself, demonstrate that such use is safe, unless the pre-1958 use is sufficient to demonstrate to qualified experts that the substance is safe when added to food.

Similarly, FDA's regulations in 21 CFR Part 170 define "scientific procedures" and establish criteria for eligibility for classification as GRAS through scientific procedures. Under 21 CFR 170.3(h), "[s]cientific procedures include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance." Under 21 CFR 170.30(b), "[g]eneral recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient." Section 170.30(b) further states that general recognition of safety through scientific procedures is ordinarily based upon published studies, which may be corroborated by unpublished studies and other data and information.

FDA's regulations in 21 CFR Part 170 define "safe" and "safety." Under 21 CFR 170.3(i), "[s]afe or safety means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." The regulation provides that, in determining safety, the following factors are to be considered: (1) The probable consumption of the substance and of any substance formed in or on food because of its use; (2) the cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet; and (3) safety factors which, in the opinion of qualified experts, are generally recognized as appropriate.

In assessing the GRAS status of Ma Huang for use in a beverage product such as "Starters' Traditional Chinese Ephedra Herbal Tea," FDA considered the criteria described above. FDA's final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids[1] describes the serious cardiovascular risks associated with ephedrine alkaloids. Although the rule applies only to dietary supplements, ephedrine alkaloids in conventional foods, such as herbal teas, have the same physiological activity and therefore present the same types of cardiovascular risks.

In addition, the Natural Medicines Comprehensive Database[2] monograph for ephedra states that ephedra is likely unsafe when used orally because it can cause severe life-threatening or disabling adverse effects in some people. The monograph notes that several case reports have linked ephedra to serious side effects including hypertension, myocardial infarction, seizure, stroke, and others. Regarding oral use during pregnancy, the monograph states that ephedra is contraindicated because it can stimulate uterine contraction.

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[1] 69 FR 6788 (Feb. 11, 2004).

[2] http://www.naturaldatabase.com

In light of these safety concerns, the use of Ma Huang in the beverage product "Starters' Traditional Chinese Ephedra Herbal Tea" does not satisfy the criteria for GRAS status outlined above. Further, FDA is not aware of any other exemption from the food additive definition that would apply to Ma Huang for use as an ingredient in beverages. Therefore, Ma Huang used in this manner is a food additive under section 201(s) of the Act and is subject to the provisions of section 409 of the Act (21 U.S.C. 348).

Under section 409, a food additive (other than a food contact substance) is deemed to be unsafe unless its use conforms to an exemption or a regulation prescribing safe conditions of use. Ma Huang (Ephedra) is not approved for use in beverages. Therefore, the product "Starters' Traditional Chinese Ephedra Herbal Tea," a beverage containing Ma Huang (Ephedra), is adulterated within the meaning of section 402(a)(2)(C) of the Act.

In addition, your "Starters' Traditional Chinese Ephedra Herbal Tea" is misbranded under section 403(q)(1) of the Act in that the nutrition information on the product label fails to comply with applicable regulations . The product is identified on the label as a food; however, the nutrition information panel is not in the format required in 21 CFR 101.9. For example, the nutrition information panel does not declare Vitamin A, Vitamin C, Vitamin E, and Zinc in the correct manner [21 CFR 101.9(d)(8)]; does not use the heading "Nutrition Facts" [21 CFR 101.9(d)(2)]; fails to include the required footnote about Percent Daily Values [21 CFR 101.9(d)(9)]; and lists substances that may not be declared in the Nutrition Facts panel, such as Taurine and Ma huang powder [21 CFR 101.9(c)].

This is not intended to be an all-inclusive review of the labeling and ingredients of your product "Starters' Traditional Chinese Ephedra Herbal Tea" or any other products marketed by your firm. It is your responsibility to ensure that foods you market are safe, properly labeled, and otherwise in compliance with all applicable legal and regulatory requirements.

The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products. You should take prompt action to correct the violations described above and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please advise this office in writing within fifteen (15) working days from your receipt of this letter as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. Please send your reply to Jennifer Thomas, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-607), 5100 Paint Branch Parkway, College Park, MD 20740.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition