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Syntech (SSPF)
International, Inc.

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VL/FDR

TO:
Division of Standards and Labeling
Regulations
Office of Nutritional Products, Labeling,
and Dietary Supplement (HFS-820)
Center for Food Safety and Applied
Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

SUPPLEMENT TO Premarket Notification
for a New Dietary Ingredient:
Betaphrine

Submitted by: MARSH B. ZHU 

Name

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SUPPLEMENT TO Premarket Notification for a New Dietary Ingredient: Betaphrine

QUESTIONS

The original notification of Betaphrine as a New Dietary ingredient contained the information required within 21 CFR §190.6 required clarification as evidenced by the inquiry from your office. The specifics of the inquiries were as follows:

- The nature of the dosage forms and detail of these forms.
- The category of the substance in accordance with Section 201(ff) of the FFDCa.

Answers

Concerning the dosage forms intended for Betaphrine and details of the dosage the following is offered for clarification:

The material Betaphrine is provided in solid dosage forms for oral consumption. Specifically, tablets and/or capsules containing Betaphrine are offered as dietary supplements. The quantity of Betaphrine contained in a single serving of dietary supplements containing Betaphrine does not exceed 80 mg of Betaphrine. Typical ranges for presentation are between 20 mg to 80 mg per serving. The recommended consumption of Betaphrine in dietary supplements is set at a maximum of 80 mg of Betaphrine per day.

The category of the substance in accordance with Section 201(ff) of the FFDCa is as follows:

- *In accordance with the Section 201(ff) for the Federal Food, Drug and Cosmetic Act (FFDCa), Betaphrine is a dietary ingredient in that it is:*
- *"A product (other than tobacco) that is intended to supplement the diet . . ."*
- *Supplements containing Betaphrine further meet the statutory definition in that they contain:*

" . . . a dietary substance for use by man to supplement the diet by increasing the total daily intake, or concentrate, metabolite, constituent, extract or combination of these ingredients."

This information is submitted as requested in duplicate and forwarded to your offices via overnight delivery. Should there be any further questions concerning this notification, please do not hesitate to contact us.

Respectfully submitted,



[Name] *Narsh B. Zhu*
[Title] *President*
Syntech (SSPF) International, Inc.