DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

MAR 29 2006

Mr. Michael Farber, MSc, President
Oral Delivery Technologies
37 Prospect Street
Nutley, New Jersey

Dear Mr. Farber:

This is to inform you that the notification, dated December 28, 2005, that you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on January 13, 2006. Your notification concerned the substances that you identified as "androsta 1,4,6 triene 3,17 dione" and "17hydroxy 6methylene androsta 1,4 diene ,3one" that you intend to market as (a) new dietary ingredient(s) in a dietary supplement product.

Your notification states that you intend to market a product consisting of a "fast dissolve citrus flavoured tablet" containing "a combination of 2.5mg of androsta 1,4,6 triene 3,17 dione ... and 2.5 mg of 17hydroxy 6methylene androsta 1,4 diene ,3one" and that the recommended or suggested conditions of use will be that "[t]he tablet is to be consumed singly or double dose twice daily for a maximum daily consumption of 20mg of the active ingredient." Your notification also states, regarding conditions of use, that "[t]he appropriate cautionary warnings with regard to potential interactions, not for use by persons with elevated blood pressure, cardiovascular disease or suspected disease or history, not for use by persons with prostate disorders or history of disorder or suspected disorders of the prostate,[ ]persons taking MAO inhibitors and other possible drug interactions, not for use by persons under age 21,[ ]not for use by women ,[ ]not for use by pregnant or lactating women , [ ]not for use by persons with diagnosed or suspected behavioural disorders, always consult a physician before commencing any diet or supplement or exercise program ,[ ]along with specific limitations as to use and the mandatory statements for dietary supplements from the FDA will be clearly shown on all labeling and advertisements."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a

conclusion. Under section 350b (a) (2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f) (1) (B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

Federal regulations found at 21 CFR 190.6 specify the requirements for a pre-market notification for a new dietary ingredient. Your notification does not comply with the requirements of 21 CFR 190.6 and is incomplete. Your submission did not include an original and two copies of the notification. In addition, copies of several of the web pages included in your notification were poorly reproduced and therefore illegible.

Moreover, it is not readily apparent whether either of the substances in the combination that is the subject of your notification are "dietary ingredients" within the meaning of 21 U.S.C. 321(ff)(1) that may be lawfully used in dietary supplements. The term "dietary supplement" is defined in 21 U.S.C. 321(ff). A dietary supplement means, among other things, a "product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
(A) a vitamin;
(B) a mineral;
(C) an herb or other botanical;
(D) an amino acid;
(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)."

Based on the information in your submission, it is unclear that either "androsta 1,4,6 triene 3,17 dione" or "17hydroxy 6methylene androsta 1,4 diene ,3one" is a "dietary ingredient" within the meaning of 21 U.S.C. 321(ff)(1). Therefore, FDA can not determine, at this time, whether your product contains a dietary ingredient(s) that may lawfully be marketed as a dietary supplement.

FDA is unable to determine whether the scientific studies cited in your notice provide an adequate basis for a conclusion that the dietary supplement will reasonably be expected to be safe because the information contained in your notice is incomplete. If you market your product without submitting a notification that meets the requirements of 21 CFR 190.6 (http://www.cfsan.fda.gov/~lrd/cfr190-6.html), or market your product less than 75 days after submitting such a notification, your product is considered adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

You indicate in your notification your intention to market a drink containing your ingredient(s). Please note that drinks are not dietary supplement products and must comply with other sections of the Act that address the ingredients of conventional foods. You may wish to contact the

Office of Food Additive Safety at the Center for Food Safety and Applied Nutrition for more information concerning the requirements for the ingredients of drinks and other conventional foods.

Your notification will be kept confidential for 90 days after the filing date of January 13, 2006. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. 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 S. Pellicore, Ph.D. at (301) 436-2375.

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