



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

Dennis Hayes
DOX, LLC
Scientific Wellness
120 North 4th Avenue
Ann Arbor, Michigan 48104

SEP 19 2006

Dear Mr. Hayes:

This is to inform you that the notification, dated June 26, 2006, you submitted pursuant to 21 U.S.C. 3501b(a)(2) (section 413 of the Federal Food, Drug, and Cosmetic Act (the Act)) was received by the Food and Drug Administration (FDA) on July 7, 2006. Your notification concerns the new dietary ingredient 19-nordehydroepiandrosterone, also referred to as 19-norDHEA, that you intend to market as a dietary supplement product called "Nucleic Acid Supplement Capsules".

According to your notice the conditions for use for the 19-norDHEA contained in tablet or capsule form are to take 100 milligrams, three times per day. The notice also states that "(t)his product is for adults over the age of 21 only. Do not exceed recommended dosage. This product is not intended to diagnose, treat, cure or prevent any disease. Keep out of reach of children".

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.

Your notification concerning "Nucleic Acid Supplement Capsules" does not comply with the requirements of 21 CFR 190.6 and is incomplete. The notification was not signed by the responsible party and was submitted with reference abstracts only. We requested three complete sets of the referenced articles but did not receive them. Therefore, we are unable to proceed any further in reviewing this notification.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Nucleic Acid Supplement Capsules," when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be 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).

Your notification will be kept confidential for 90 days after the filing date of July 7, 2006. After the 90-day date, the notification will be placed on public display at FDA's Division of Docket Management 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 Victoria Lutwak at (301) 436-1775.

Sincerely yours,

A handwritten signature in black ink that reads "Linda S. Pellicore". The signature is written in a cursive style with a large initial "L" and "P".

Linda S. Pellicore, Ph.D.
Supervisory Team Leader, Senior Toxicologist
Division of Dietary Supplement Programs
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and Dietary Supplements
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