DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

MAR 1 1 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Schwartz Laboratories
6905 Plainfield Rd
Cincinnati, OH 45236

Dear Sir or Madam:

This letter concerns your product Andro Trybulen that is labeled and/or promoted as a dietary supplement. The product labeling declares androstenedione (among other names, also called 4-androstenedione or 4-androstene-3,17-dione) as an ingredient.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff) [section 201(ff) of the Federal Food, Drug, and Cosmetic Act (the Act)]. Given that you have labeled your product as a dietary supplement, we assume you have a basis to conclude that androstenedione is a "dietary ingredient" under 21 U.S.C. 321(ff)(1). Assuming that androstenedione is a "dietary ingredient," it would also be a "new dietary ingredient" for which a notification is required under 21 U.S.C. 350b(a)(2) and 21 CFR 190.6.

Under 21 U.S.C. 350b, a dietary supplement that contains a new dietary ingredient (i.e., a dietary ingredient not marketed in the United States before October 15, 1994) shall be deemed adulterated under 21 U.S.C. 342(f) unless it meets one of two requirements:

> (1) The dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or
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> (2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

FDA is not aware of any information demonstrating that androstenedione was lawfully marketed as a dietary ingredient in the United States before October 15, 1994. Nor is FDA aware of any information demonstrating that this ingredient has been present in the food

supply as an article used for food in a form in which the food has not been chemically altered. In the absence of such information, androstenedione is subject to the notification requirement for a new dietary ingredient in 21 U.S.C. 350b(a)(2) and 21 CFR 190.6. Because you have not submitted the required notification, your product is adulterated under 21 U.S.C. 342(f)(1)(B) and 350b(a).

Even if the required notification had been submitted, based on what we know now, we know of no evidence that would establish that your product is not adulterated. In the absence of a history of use or other evidence of safety establishing that androstenedione, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe, a product containing androstenedione is adulterated under 21 U.S.C. 342(f)(1)(B) and 350b(a) 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). FDA is aware of no history of use or other evidence of safety establishing that androstenedione will reasonably be expected to be safe as a dietary ingredient. In the absence of such history of use or other evidence, your product would be considered adulterated.

We request that you take prompt action to correct these and any other violations associated with Andro Trybulen and any other products marketed by your firm that contain the dietary ingredient androstenedione. We also remind you that the new dietary ingredient notification requirement applies to all dietary supplements that contain new dietary ingredients that have not been present in the food supply as articles used for food in a form in which the food has not been chemically altered.

Failure to immediately cease distribution of the product could result in enforcement action by FDA without further notice. The Act provides for seizure of violative products, injunction against the manufacturers and distributors of violative products, and criminal sanctions against persons responsible for causing violations of the Act.

We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace, and an explanation of each step taken to assure that similar violations do not recur. Your reply should be directed to Jennifer Thomas, Compliance Officer, at the above address.

Sincerely,

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