



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

DEC 6 2004

Ms. Tomasina Uboldi  
Department of Exterior Commerce  
Naturasol  
Carrera 13 No. 46-56  
Bogotá, Columbia

Dear Ms. Uboldi:

This is to inform you that the notification, dated September 21, 2004, 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 September 23, 2004. Your notification concerns the substance called "Vira Vira" that you describe as dehydrated plant material of *Achyrocline satureioides* (Lam.) DC. that you intend to market as a new dietary ingredient.

According to the notification, Naturasol intends to sell the proposed new dietary supplement in tablet form of which 81.5% (by weight) of dehydrated plant material, *Achyrocline satureioides* (Lam.) DC., will be present in a 500 mg tablet. The tablet will also contain 16% (by weight) of starch, 1.5% arabic gum, and 1% magnesium stearate. The notification states that "the normal use recommended on the label of "Vira Vira" is as a dietary supplement. Take 2 or 3 tablets three times a day." The notification further states that "women who intend to get pregnant or are pregnant or nursing should not take "Vira Vira"".

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.

FDA has carefully considered the information in your submission, and the agency has concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing “Vira Vira” will reasonably be expected to be safe.

Federal regulations found at 21 CFR 190.6 specify the requirements for a pre-market notification of a new dietary ingredient. The notification you sent us concerning “Vira Vira” does not comply with the regulation set forth in 21 CFR 190.6(b)(4). Your notification contains a number of published articles and pages from various botanical handbooks. However, you failed to provide complete English translations of all submitted information. This precludes an accurate evaluation of your information.

Your notification states that there is a long history of use of “Vira Vira”. However, there is no documentation in your notification that supports this claim.

In addition, your notification fails to clearly identify the composition of the new dietary ingredient “Vira Vira” and it fails to clarify the relationship between the composition of the materials used in the various test reports and the composition of the substance you call “Vira Vira”. Therefore, it is not evident that the test substances used in the referenced studies are qualitatively or quantitatively similar to your new dietary ingredient, “Vira Vira”. Your notification does not explain how these studies are relevant to evaluating the safe use of your ingredient under the recommended conditions of use.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that your product containing “Vira Vira”, 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 September 23, 2004. 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 Linda Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,

*for Robert J. Moore*

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