



MAY - 7 2004

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

Yu Har Fei, President
Nano Port (USA), Inc.
3380 Sheridan Drive, Suite 262
Amherst, New York 14226

Dear Mr. Yu Har Fei:

This is to inform you that the notification, dated February 9, 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 February 23, 2004. Your notification concerns the substance, Nano Red Elemental Selenium under the trade name of Nano-Se, that you intend to market as a new dietary ingredient.

You state that "the level of new dietary ingredient within a supplement will be 45 micrograms (mcg) of selenium (Nano Red Elemental Selenium) in each capsule. The conditions of use are to take one to two capsules 1 to 2 times daily or as directed by a health professional."

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 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 significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing Nano Red Elemental Selenium (Nano-Se) will reasonably be expected to be safe.

We indicated in our letter, dated August 19, 2003, in response to your previous notification filed by FDA on June 4, 2003, that you provided inadequate information about the chemical identity of your substance called Nano Red Elemental Selenium (Nano-Se). In the present notification, you failed to provide any additional information to clarify the identity of your substance, Nano Red Elemental Selenium (Nano-Se). A description of the method of manufacture or process of obtaining your product, Nano Red Elemental Selenium (Nano-Se), may have helped FDA clarify the identity of your product.

Further, in FDA's August 19, 2003 letter to you, we stated that most of the studies you referenced did not use your substance, Nano Red Elemental Selenium (Nano-Se), as the test article. In other studies you submitted in the present notification and in the previous notification filed by FDA on June 4, 2003, it is unclear whether the test substances used are qualitatively and quantitatively the same as your substance. For example, in the reference identified as Attachment 3 "Report on a 90-day subchronic toxicity test on Xiwang capsule in rats," it is unclear if the test substance used in the report is the same as your product. Further, one referenced study that appeared to use your substance focused primarily on bioavailability and antioxidant effects and not on safety. No additional safety information or data specific to your product, Nano Red Elemental Selenium (Nano-Se), was provided in the present notification. Therefore, this notification did not provide any additional information to support a reasonable expectation of safety for Nano Red Elemental Selenium (Nano-Se).

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that Nano Red Elemental Selenium (Nano-Se), 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 an 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 February 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 Victoria Lutwak 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