DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

1265 '03 MAR 19 P2:25

Date: March 18, 2003

From: Consumer Safety Officer, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-821

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification:	Nano-Se
Firm:	NanoPort (U.S.A.) Inc.
Date Received by FDA:	December 19, 2002
90-Day Date:	March 19, 2003

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Victoria Lutwak

Victoria Lutwak

Attachments

95S-0316

RPT161

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

MAR - 4 2003 1266 '03 MAR 19 P2:25

Mr. Yu Har Fei
President
Nano Port (USA) Inc.
317 West 35th Street, Apt 3FE
New York, New York 10001

Dear Mr. Yu:

Please refer to your 75 day New Dietary Ingredient Notification (NDI) dated November 18, 2002, received December 19, 2002, submitted under section 21 U.S.C. 350b(a)(2) of the Federal Food, Drug, and Cosmetic Act for Nano-Se.

We also refer to our telephone message on January 6, 2003, that we received two copies of the NDI and two of the twelve references, making your notification incomplete. To date, we have had no reply from you.

We have completed our administrative review of the NDI, and we find the information presented does not meet the submission requirements for a premarket notification under section 21 CFR 190.6.

The deficiencies may be summarized as follows:

1. 21 CFR 190.6 (a) We received two copies of the notification. You need to submit an original and two copies of this notification.

2. 21 CFR 190.6 (b)(4) Submit copies of any references to published information offered in support of the notification in reprint or legible photostatic form. Any documents in a foreign language shall be accompanied by an accurate and complete English translation.

Therefore, you have not met the requirement to notify FDA of the basis upon which you have concluded that a dietary supplement containing Nano-Se is reasonably expected to be safe as required by 21 U.S.C. 350b(a)(2) and 21 CFR 190.6. Accordingly, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a

dietary supplement that contains new dietary ingredient(s) for which there is inadequate information to provide reasonable assurance that it does not present a significant or unreasonable risk of illness or injury. Introduction of such products into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

You may send a new notification (in triplicate) to correct the deficiencies identified above.

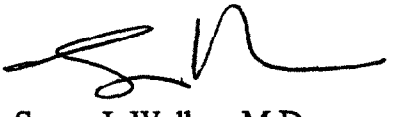
We note that the required information was not received within the 75-day notification period. Your NDI notification will placed on public display in the FDA's Docket Management Branch, in docket number 95S-0316, under section 21 CFR 190.6(e), 90 days from the effective filing date. Prior to the 90-day period, you may wish to identify in writing specifically what information you believe is proprietary in your current notification for FDA's consideration.

To help you with you notification, please consult the following FDA Internet sites and their corresponding links:

http://www.cfsan.fda.gov/~dms/supplmnt.html
http://www.cfsan.fda.gov/~lrd/fr97923e.html (21 CFR 190.6)

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-1775.

Sincerely yours,



Susan J. Walker, M.D.
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