



MAR 12 2003 1387 '03 MAR 24 P1:52

Mr. Scott D. Kumpf  
General Counsel and Corporate Secretary  
Natural Balance  
3155 N. Commerce Court  
Castle Rock, Colorado 80104

Dear Mr. Kumpf:

This is in response to your letter of February 3, 2003 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Natural Balance is making the following claims, among others, for its product **No-Rad™** :

- “Protect your family against the absorption of radioactive iodine after a nuclear emergency;”
- “...protects your thyroid gland from the radioactive iodine which can be released during a nuclear accident or attack;”
- “This blocks the uptake of radioactive iodine, protecting you from its harmful effects;”
- “The good news is that taking Potassium Iodide (KI) before exposure helps to protect you from the damaging effects of radioactive iodine;”
- “...effectively blocking the uptake of radioactive iodine;”
- “Once the thyroid is saturated, then any additional radioactive iodine that is later inhaled or ingested is quickly eliminated via the kidneys.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to prevent disease (i.e., radiation poisoning or radiation sickness). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.


975-0163

LET677

Page 2 - Mr. Scott D. Kumpf

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJ Walker', with a long horizontal flourish extending to the right.

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

**Copies:**

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Denver District Office, Office of Compliance, HFR-SW240

February 3, 2003

FEB 21 2003

Office of Special Nutritionals  
(HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington, D.C. 20204

Dear Sir or Madam:

Enclosed please find written notification for the following Natural Balance products whose labeling includes one or more statements listed in Section 403(r) of the Federal Food, Drug and Cosmetic Act.

- (1) No-Rad™

Please contact me if you have any questions or need any additional information.  
Thank you.

Sincerely,



Scott D. Kumpf  
General Counsel and Corporate Secretary

Enclosures

83462

NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 C.F.R. § 101.93

This notification is being filed on behalf of Natural Balance, Inc., 3130 N. Commerce Court, Castle Rock, CO 80109, which is the manufacturer of the product which bears the statements identified in the Notification. This Notification is being made pursuant to Section 6 of DSHEA and 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling statements appears is NoRad™.

The text of each structure-function statement for which notification is now being given is:

- Statement 1: *Protect your family against the absorption of radioactive iodine after a nuclear emergency.*
- Statement 2: *No-Rad contains Potassium Iodide which protects your thyroid gland from the radioactive iodine which can be released during a nuclear accident or attack.*
- Statement 3: *When you take Potassium Iodide, your thyroid gland absorbs as much normal iodine as it can hold. This blocks the uptake of radioactive iodine, protecting you from its harmful effects.*
- Statement 4: *Certain forms of Iodine help the thyroid gland work properly.*
- Statement 5: *The good news is that taking Potassium Iodide (KI) before exposure helps to protect you from the damaging effects of radioactive iodine.*
- Statement 6: *It fills up your thyroid gland with safe, stable iodine, effectively blocking the uptake of radioactive iodine.*
- Statement 7: *Once the thyroid is saturated, then any additional radioactive iodine that is later inhaled or ingested is quickly eliminated via the kidneys.*

The following summary identifies the dietary ingredient(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1.	Potassium Iodide (KI)
2.	Potassium Iodide (KI)
3.	Potassium Iodide (KI)
4.	Potassium Iodide (KI)
5.	Potassium Iodide (KI)
6.	Potassium Iodide (KI)
7.	Potassium Iodide (KI)

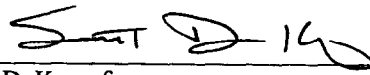
NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA AND 21 C.F.R. § 101.93  
No-Rad™

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1.	No-Rad™	Label
2.	No-Rad™	Label
3.	No-Rad™	Label
4.	No-Rad™	Label (Package Insert)
5.	No-Rad™	Label (Package Insert)
6.	No-Rad™	Label(Package Insert)
7.	No-Rad™	Label(Package Insert)

I, Scott D. Kumpf, am authorized to certify this Notification on behalf of Natural Balance, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that Natural Balance, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date : 2-03-03

By:   
Scott D. Kumpf

Title: General Counsel and Corporate Secretary