



NOV - 4 1997

0563 '98 MAR 24 P2:43

Mr. Michael Purles  
General Manager  
The Right Solution  
500 E. Cheyenne Avenue  
N. Las Vegas, Nevada 89030

Dear Mr. Purles:

This is in response to your letter of October 23, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that The Right Solution is making the following claims for the product PR10:

"Pain Relief to the power of 10"

"PR10 provides penetrating warmth as it relieves pain"

"For temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backaches, strains, sprains, and bruises"

Section 403(r)(6) of the act 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 the product "PR10" suggest that it is intended to treat, mitigate, or cure a disease, namely pain, and specifically, pain associated with arthritis, simple backaches, strains, sprains, and bruises. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, 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.

We also note that one claim (PR10 provides penetrating warmth as it relieves pain) suggests that the product may be intended for topical use and not be intended to be ingested. Section 201(ff)(2)(A)(i) of the act defines a dietary supplement, in part, as a product "intended for ingestion." Therefore, a product intended for topical application to the body does not meet the statutory definition of a dietary supplement and, if making a claim to treat, cure, prevent, or mitigate pain, is a drug under sections 201(g)(1)(B) or 201(g)(1)(C) of the act.

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LET 123

Page 2 - Mr. Michael Purles

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.  
Acting Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
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, San Francisco District, Compliance Office, HFR-PA140

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO, JGordon)  
HFS-456 (File)  
HFS-450 (w/cpy incoming, r/f)  
HFD-310 (Williams)  
HFD-314 (Aronson)  
HFS-600 (Reynolds)  
HFS-605 (Bowers)  
r/d:HFS-456:RMoore:11/03/97  
f/t:HFS-456:rjm:11/03/97:docname:purles.adv:disc24

NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR §101.93

RECEIVED  
11/3/97

This notification is being filed on behalf of The Right Solution which is the Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 500 E. Cheyenne Ave., N. Las Vegas, NV 89030. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is PRIO.

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

(Statement 1): Pain Relief to the power of 10.

(Statement 2): PRIO provides penetrating warmth as it relieves pain.

(Statement 3): For temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backaches, strains, sprains, and bruises.

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

Statement Number                      Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement

- 1. Capsaicin
- 2. Capsaicin
- 3. Capsaicin

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.	PRIO	Yes
2.	PRIO	YES
3.	PRIO	Yes
4.		

I, Michael S. Purles, am authorized to certify this Notification on behalf of The Right Solution. I certify that the information presented and contained in this Notification is complete and accurate, and that Capsaicin has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: Oct 23, 1997 By: Michael Purles  
[Name] Michael Purles  
[Title] General Manager

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