



0018 7 OCT -2 P12:42

SEP 28 2007

Ms. Jean M. Trimbo  
Integrity  
201 Field End Street  
Sarasota, Florida 34240

Dear Ms. Trimbo:

This is in response to your letters to the Food and Drug Administration (FDA) dated September 7, 2007 pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Your notices state that Integrity is making the claims "Supports healthy cholesterol levels," "Supports healthy blood pressure," and "Supports healthy glucose levels" for the product NutraVitals Cinnulin PF and the claims "Supports healthy blood pressure" and "Supports healthy glucose levels" for the product iVitals Cinnulin PF.

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about blood pressure and blood glucose. Because the claims you are making for these products represent that the products are intended to affect blood cholesterol, blood glucose, and blood pressure but do not also include a statement about them being intended to affect blood cholesterol, blood glucose and blood pressure that are already in the normal ranges, they are implied disease claims.

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 these products suggest that they are intended to treat, prevent, or mitigate diseases, including wound healing and allergies. These claims do not meet the requirements of 21 U.S.C. 343(r)(6).

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Page 2 - Ms. Jean M. Trimbo

These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855. Please contact us if we may be of further assistance.

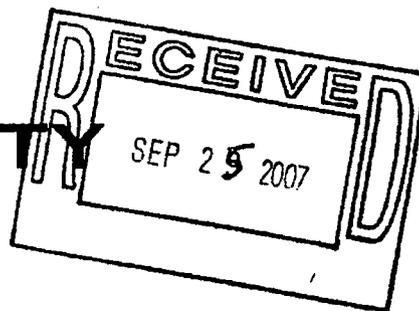
Sincerely yours,



Vasilios H. Frankos, Ph.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutrition, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

**Copies:**

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Florida District Office, Office of Compliance, HFR-SE240



September 7, 2007

Office of Nutritional Products, Labeling and Dietary Supplement (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

Re: Integrity's Notification of Structure and Function Claims for Our Label  
iVitals™ Cinnulin PF® under 21 CFR 101.93

Dear Sir or Madame,

In accordance to 21 CFR 101.93, Integrity hereby notifies FDA that it is using the following label for its product iVitals™ Cinnulin PF®.

Please find an original and three copies of a notification of structure and function claims for iVitals™ Cinnulin PF®. We ask you to kindly sign and date stamp one of the three copies of the notification, returning that signed and date-stamped copy to our attention as evidence of our filing of this notification. Please find enclosed a self addressed stamped envelope to return the date-stamped and signed copy.

I certify that the foregoing is complete and accurate and that Integrity has substantiation that the statements are truthful and not misleading.

Sincerely,

*Jean M. Trimbo*

Jean M. Trimbo  
QA and Compliance Coordinator

Attachment: iVitals™ Cinnulin PF®

*2067-6709*

201 Field End Street \* Sarasota, FL 34240  
(941) 342-0007 \* (941) 342-7337

Cinnulin PF is a clinically tested water soluble cinnamon extract that filters out toxins found in table and whole cinnamon, and the only extract standardized for Type-A Polymer actives identified by USDA research. Natural and safe for every day use, it contains no sugar, starch, artificial colors, flavors, salt, yeast, barley, gluten, wheat, corn, dairy products, yeast, milk derivatives or preservatives.

**WARNING:** As with any dietary supplement, consult with your physician prior to use.

**STORAGE:** Store in a cool, dry place out of the reach of children.

\* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Cinnulin PF is a registered trademark of Integrity.

Helps metabolic syndrome factors by supporting healthy:  
glucose levels\*  
blood pressure\*  
body composition\*

# Cinnulin PF®

Proprietary Cinnamon Extract



DIETARY SUPPLEMENT  
120 Capsules | 250 mg

iVitals™

#### RECOMMENDED USE:

For adults, take 1-2 capsules daily prior to meals. For best results, take one capsule prior to AM meal, and one capsule prior to PM meal.

#### Supplement Facts

Serving Size: 1 Capsule  
Servings Per Container: 120

Amount Per Serving	% Daily Value
Cinnulin PF® 250 mg (Cinnamomum Aromaticum) water extract (bark) [standardized to 0.3% (7.5 mg) Trimeric and Tetrameric A-Type Polymers]	†
† Daily Value Not Established	

Other ingredients: Gelatin, Microcrystalline Cellulose and Magnesium Stearate.

MANUFACTURED BY:  
Integrity, 201 Field End Street, Sarasota FL 34240  
800.479.6383 / www.i-Vitals.com



# INTEGRITY

RECEIVED  
9/27/07

September 7, 2007

Office of Nutritional Products, Labeling and Dietary Supplement (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

Re: Integrity's Notification of Structure and Function Claims for Our Label  
NutraVitals™ Cinnulin PF® under 21 CFR 101.93

Dear Sir or Madame,

In accordance to 21 CFR 101.93, Integrity hereby notifies FDA that it is using the following label for its product NutraVitals™ Cinnulin PF®.

Please find an original and three copies of a notification of structure and function claims for NutraVitals™ Cinnulin PF®. We ask you to kindly sign and date stamp one of the three copies of the notification, returning that signed and date-stamped copy to our attention as evidence of our filing of this notification. Please find enclosed a self addressed stamped envelope to return the date-stamped and signed copy.

**WARNING:** Consult with a physician prior to use.

Keep out of the reach of children.  
Store in a cool, dry place.

\* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



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nutraVitals™

## Cinnulin PF®

Patented Cinnamon Water Extract

Supports healthy glucose levels\*  
Supports healthy cholesterol levels\*  
Supports healthy blood pressure\*

120 Capsules

**RECOMMENDED USE:**  
Take 1 capsule 2-3 times daily before mealtimes.

### Supplement Facts

Serving Size: 1 Capsule  
Servings Per Container: 120

Amount Per Serving	% Daily Value
Cinnulin PF® 125 mg (aqueous cinnamon bark extract)	†
† Daily Value Not Established	

Other ingredients: Gelatin & Magnesium Stearate.

MANUFACTURED IN THE USA FOR:  
nutraVitals, 201 Field End St, Sarasota FL 34240  
1.800.479.6363 / www.nutravitals.com

201 Field End Street \* Sarasota, FL 34240  
(941) 342-0007 \* (941) 342-7337

1955

07-6709

I certify that the foregoing is complete and accurate and that Integrity has substantiation that the statements are truthful and not misleading.

Sincerely,

*Jean M. Trimbo*

Jean M. Trimbo  
QA and Compliance Coordinator