



AUG 25 2000

730 10 SEP -5 2000

Ms. Judy Hennessy
Wind River Herbs
P.O. Box 3637
Alpine, Wyoming 83128

Dear Ms. Hennessy:

This is in response to your letter of August 1, 2000 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 Wind River Herbs is making the following claim for the product Womens Pau D'Arco Blend:

“Maintains healthy levels of candida yeast in women.”

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 statement that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely, candida yeast infections. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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.

Please contact us if we may be of further assistance.

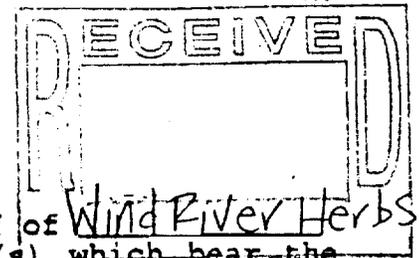
Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

975-0163

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



This notification is being filed on behalf of Wind River Herbs which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: Lincoln County Rd. 108 #32 P.O. Box 3637 Alpine WY 83128. 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 Womens Pau D'Arco Blend

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

- (Statement 1): Maintains healthy levels of candida yeast in women
- (Statement 2):
- (Statement 3):

The following summary identifies the dietary ingredient(s) or supplement(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.	<u>Pau D'Arco, Black walnut, calendula, myrrh, Echinacea angustifolia + purpurea, pricklyash, tomatum</u>
2.	
3.	

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.	<u>Womens Pau D'Arco Blend</u>	
2.		
3.		

I, Judy Hennessy, am authorized to certify this Notification on behalf of Wind River Herbs. I certify that the information presented and contained in this Notification is complete and accurate, and that Wind River Herbs has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: June 6, 2000 By: Judy Hennessy
[Name]
[Title]

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