



JUN 28 2001

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Mr. Ronald C. Sappington
Royal Farms Inc
50 E 100 S. Ste. 205
St. George, Utah 84770

Dear Mr. Sappington:

This is in response to your letter of June 4, 2001 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 Royal Farms Inc. is making the following claim, among others, for the product **Noni (Morinda Citrifolia)**:

“Noni significantly increases your T-cell count.”

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, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim 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.

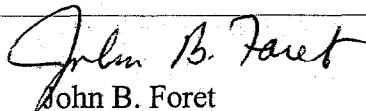
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Please contact us if you require further assistance.

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

Copies:

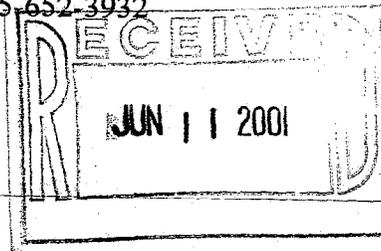
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

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

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



Royal Farms Inc.
50 E. 100 S. Ste. 205
St. George, Utah 84770
435-628-6715 ~ fax 435-652-3932



4 June 2001

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

76308

To the Food and Drug Administration,

Pursuant to section 403(r)(6) for the Federal Food, Drug, and Cosmetic Act (FDC Act), 21.U.S.C. §343 (r)(6), We hereby notify the FDA that Royal Farms Inc., has included the following statements in labeling for a dietary ingredient that it markets for use as a dietary supplement. This statement will be used for all of our products in advertising literature.

The following information is provided:

- 1) Royal Farms Inc., 50 E. 100 S. Ste. 205, St. George, UT 84770
- 2) The text of the statement is, "Noni significantly increases your T-cell count".
- 3) The product: various products using Noni (*Morinda Citrifolia*) as an ingredient.
- 4) The dietary ingredient that is the subject of the statement is Noni (*Morinda Citrifolia*).

Pursuant to FDA regulations concerning notification procedures for certain types of statements on dietary supplements, 21 C.F.R. §101.93. I certify that to the best of my knowledge and in my opinion, the information contained in this notice is complete and accurate, and that Royal Farms Inc. has substantiation that the statements are truthful and not misleading.

Sincerely,

Ronald C. Sappington
Director of Compliance and Quality Assurance
Royal Farms Inc.