



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUN 11 2001 895 '01 JUL -2 P157

Ms. Sherilyn R. Lucas
Administrative Assistant
Nutraceutical Products Company
735-L Park
St. Castle Rock, Colorado 80104

Dear Ms. Lucas:

This is in response to your letter of May 30, 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 Nutraceutical Products Company, doing business as NUPRO, is making the following claim for the product **ProPara Formula**:

“Parasite management.”

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 a disease. 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.

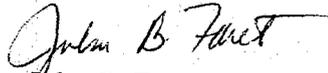
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Please contact us if you require further assistance.

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 Compliance, HFR-SW240

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-810 (Foret)

HFS-811 (file)

HFD-310

HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:6/7/1:docname:76251.adv:disc58

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

JUN 1 2001

This notification is being filed on behalf of Nutraceutical Products Company, dba NUPRO which is the marketer of the product(s) which bear the statements identified in this notification. Its business address is: 735-L Park St, Castle Rock, CO 80104. 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 **ProPara**.

The text of each structure-function statement for which notification is now being given is:
(Statement 1)

Parasite Management

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>
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1.	ProPara Formula
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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	ProPara	NUPRO

I, _____, am authorized to certify this Notification on behalf of Nutraceutical Products Company, dba NUPRO. I certify that the information presented and contained in this Notification is complete and accurate, and that Nutraceutical Products Company, dba NUPRO has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 5, 30, 2001

By: Sherilyn R. Lucas
Sherilyn R. Lucas
Administrative Assistant

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