



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

Ms. Barbara Larkin  
Regulatory Affairs  
L. Perrigo Company  
117 Water Street  
Allegan, Michigan 49010

FEB 16 2000

1 7 3 7 '00 FEB 29 P2:12

Dear Ms. Larkin:

This is in response to your letters of January 21, 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 submissions state that Perrigo Company is making the following claims, among others, for the product **"Daily Source Soy Formula:"**

"For Bone and Menopausal Health;"

"Contributes to Health Bones and Supports the Body Through Natural Changes;"

"Maintaining healthy bones during and after menopause."

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 this product suggest that it is intended to treat, prevent, or mitigate a disease, namely bone loss, or osteoporosis, in post-menopausal women. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims 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.

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

LET 342

Page 2 - Ms. Barbara Larkin

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, Chicago District Office, Office of Compliance, HFR-MW140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (r/f, file)

HFS-450 (r/f, file)

HFD-310

HFD-314 (Aronson)

HFS-605 (Bowers)

HFV-228 (Benz)

GCF-1 (Nickerson, Barnett, Dorsey)

f/t:HFS-456:rjm:2/11/00:docname:69116.adv:disc44

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

## NOTIFICATION OF DIETARY SUPPLEMENT CLAIMS

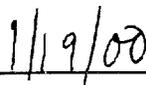
|  |   |  |
|--|---|--|
| <b>Manufacturer Name and Address:</b><br><br><b>Perrigo Company of South Carolina</b><br><b>117 Water Street</b><br><b>Allegan, MI 49010</b>   |   |  |
| <b>Statement Text:</b><br><b>For Bone and Menopausal Health</b>  |   |  |
| <b>Dietary Ingredient:</b><br><b>Soy Isoflavone Compound (from</b><br><b>Novasoy®) (formula also contains</b><br><b>Calcium and Vitamin D)</b> | <b>Dietary Supplement Name:</b><br><b>Soy Formula</b> |  |
| <b>Appears on the following labels:</b><br><b>Daily Source</b>   |   |  |
|  |   |  |
|  |   |  |
|  |   |  |
|  |   |  |

I hereby certify that the information presented and contained in this notice is complete and accurate.

I also certify that Perrigo Company has substantiation to verify that the statement is truthful and not misleading.

  
\_\_\_\_\_

(Responsible Individual Signature)

  
\_\_\_\_\_

(Date)

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Office for Special Nutritionals (HFS-450)  
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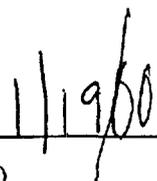
## NOTIFICATION OF DIETARY SUPPLEMENT CLAIMS

|  |   |  |
|--|---|--|
| <b>Manufacturer Name and Address:</b><br><br><b>Perrigo Company of South Carolina<br/>117 Water Street<br/>Allegan, MI 49010</b>   |   |  |
| <b>Statement Text:</b><br><b>Contributes to Healthy Bones and Supports the Body Through Natural Changes</b>                        |   |  |
| <b>Dietary Ingredient:</b><br><b>Soy Isoflavone Compound (from<br/>Novasoy®) (formula also contains Calcium<br/>and Vitamin D)</b> | <b>Dietary Supplement Name:</b><br><b>Soy Formula</b> |  |
| <b>Appears on the following labels:</b><br><b>Daily Source</b>   |   |  |
|  |   |  |
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\_\_\_\_\_  
(Responsible Individual Signature)

  
\_\_\_\_\_  
(Date)

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 Office for Special Nutritionals (HFS-450)  
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## NOTIFICATION OF DIETARY SUPPLEMENT CLAIMS

|   |                                 |  |
|---|---------------------------------|--|
| <b>Manufacturer Name and Address:</b>   |                                 |  |
| <b>Perrigo Company of South Carolina<br/>         117 Water Street<br/>         Allegan, MI 49010</b>   |                                 |  |
| <b>Statement Text:</b>  |                                 |  |
| <p><b>Research suggests that certain individuals may benefit from consuming a diet high in soy. Isoflavones are considered to be the active compounds which may naturally provide support for:</b></p> <ul style="list-style-type: none"> <li>▪ <b>women's nutritional needs during menopause</b></li> <li>▪ <b>maintaining healthy bones during and after menopause</b></li> </ul> |                                 |  |
| <b>Dietary Ingredient:</b>  | <b>Dietary Supplement Name:</b> |  |
| <b>Soy Isoflavone Compound (from Novasoy®) (formula also contains Calcium and Vitamin D)</b>  | <b>Soy Formula</b>              |  |
| <b>Appears on the following labels:</b>   |                                 |  |
| <b>Daily Source</b>   |                                 |  |
|   |                                 |  |
|   |                                 |  |
|   |                                 |  |
|   |                                 |  |

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 \_\_\_\_\_  
 (Responsible Individual Signature)

\_\_\_\_\_  
 11/19/00  
 \_\_\_\_\_  
 (Date)