

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

3/11/99

B282 '99 MAR 15 P2:01

This notification is being filed on behalf of Natural Balance, Inc., 3130 N. Commerce Court, P. O. Box 8002, Castle Rock, CO 80104 – 8002, which is the manufacturer of the product which bears the statements identified in the Notification. 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 statements appears is Moducare™ Sterinol™.

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

- Statement 1: *Exciting new clinical research demonstrates that supplementation with the exact combination of sterols and sterolins found in Moducare™ Sterinol™ can play an important role in optimizing your body's immune function.*
- Statement 2: *Two naturally-occurring plant compounds, sterols and sterolins, have been found to provide significant immune-regulating benefits.*
- Statement 3: *In particular, plant fats, as found in Moducare™ Sterinol™, are especially useful in enhancing the body's ability to regulate immune function.*

The following summary identifies the dietary ingredient(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.	<i>Sterols, Sterolins</i>
2.	<i>Sterols, Sterolins</i>
3.	<i>Sterols, Sterolins</i>

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.	<i>Moducare™ Sterinol™</i>	<i>Printed Box – 90 Capsules Label – 90 Capsules</i>
2.	<i>Moducare™ Sterinol™</i>	<i>Printed Box – 90 Capsules</i>
3.	<i>Moducare™ Sterinol™</i>	<i>Printed Box – 90 Capsules</i>

I, Patricia L. Vazquez, am authorized to certify this Notification on behalf of Natural Balance, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that Natural Balance, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 3.2.99

By: *Patricia L. Vazquez*

Title: *Director, Regulatory Affairs*

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