

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

RECEIVED
12/14/98

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 Cardio-TMG™.

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

- Statement 1: *Advanced TMG and Folic Acid Cardiovascular Formula*
- Statement 2: *Helps Reduce Homocysteine Levels*
- Statement 3: *Helps Promote Vascular Health*
- Statement 4: *Breakthrough scientific research indicates that the specific ingredients in Cardio-TMG provide for vascular health by promoting proper Homocysteine metabolism.*
- Statement 5: *Studies suggest that Trimethylglycine (TMG), in combination with other essential nutrients, deactivates Homocysteine by converting it into the beneficial amino acid, Methionine.*
- Statement 6: *Cardio-TMG from Natural Balance combines lab-tested TMG with significant amounts of Vitamins B-6, B-12, Folic Acid and other natural ingredients which promote arterial health and optimum cardiovascular function.*
- Statement 7: *Only Cardio-TMG combines a complete range of those lab-tested, quality ingredients which studies indicate may help contribute to healthy arteries.*
- Statement 8: *TMG (trimethylglycine). TMG, a natural compound, is an important source of methyl groups necessary for the conversion of Homocysteine to beneficial Methionine.*
- Statement 9: *Vitamins B-6, B-12, Folic Acid. Essential vitamins which contribute to the biochemical pathways that reduce homocysteine.*
- Statement 10: *Vitamin E. This important antioxidant helps promote cardiovascular health.*
- Statement 11: *Inositol and Choline. Lipotropic nutrients which promote effective fat metabolism.*

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>TMG (trimethylglycine), Folic Acid</i>
2.	<i>TMG (trimethylglycine), Folic Acid</i>

Cardio-TMG™

3. *TMG (trimethylglycine), Folic Acid, Vitamin E, Inositol Hexanicotinate, Vitamin B-6, Vitamin B-12, Choline*
4. *TMG (trimethylglycine), Folic Acid, Vitamin B-6, Vitamin B-12*
5. *TMG (trimethylglycine), Folic Acid, Vitamin B-6, Vitamin B-12*
6. *TMG (trimethylglycine), Folic Acid, Vitamin E, Inositol Hexanicotinate, Vitamin B-6, Vitamin B-12, Choline*
7. *TMG (trimethylglycine), Folic Acid, Vitamin B-6, Vitamin B-12, Vitamin E*
8. *TMG (trimethylglycine)*
9. *Vitamins B-6, B-12, Folic Acid*
10. *Vitamin E*
11. *Inositol and Choline*

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>Cardio-TMG™</i>	<i>Printed Box – 60 Capsules Label – 60 Capsules</i>
2.	<i>Cardio-TMG™</i>	<i>Printed Box – 60 Capsules</i>
3.	<i>Cardio-TMG™</i>	<i>Printed Box – 60 Capsules Label – 60 Capsules</i>
4.	<i>Cardio-TMG™</i>	<i>Printed Box – 60 Capsules</i>
5.	<i>Cardio-TMG™</i>	<i>Printed Box – 60 Capsules</i>
6.	<i>Cardio-TMG™</i>	<i>Printed Box – 60 Capsules</i>
7.	<i>Cardio-TMG™</i>	<i>Printed Box – 60 Capsules Label – 60 Capsules</i>
8.	<i>Cardio-TMG™</i>	<i>Printed Box – 60 Capsules Label – 60 Capsules</i>
9.	<i>Cardio-TMG™</i>	<i>Printed Box – 60 Capsules</i>

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Cardio-TMG™

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|-----|-------------|---------------------------|
| 10. | Cardio-TMG™ | Printed Box – 60 Capsules |
| 11. | Cardio-TMG™ | Printed Box – 60 Capsules |

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: 12.7.98

By:

Title:

Patricia L. Vazquez
Regulatory Affairs