

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

RECEIVED
12/4/98

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 Ipriflavone.

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

- Statement 1: *Advanced Bone Support*
- Statement 2: *For years Ipriflavone (7-isopropoxy-isoflavone) has been popular in Europe for helping maintain healthy bones.*
- Statement 3: *Although Ipriflavone is not calcium, studies indicate it is significantly more effective than Calcium alone to help maintain bone strength.*
- Statement 4: *Clinical studies have shown that Ipriflavone offers these specific, unique health benefits:*
- *Increases Calcium retention.*
 - *Enhances Calcium utilization.*
 - *Maintains bone mass.*
- Statement 5: *An amazing nutritional compound from Europe, Ipriflavone (7-isopropoxy-isoflavone) is a bone enhancing nutrient found naturally in alfalfa and bee propolis.*
- Statement 6: *In fact, studies have shown that 600 mg of Ipriflavone per day increased calcium retention and utilization.*
- Statement 7: *Nutritional Breakthrough in Bone Health!*

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>Ipriflavone (7-isopropoxy-isoflavone)</i>
2.	<i>Ipriflavone (7-isopropoxy-isoflavone)</i>
3.	<i>Ipriflavone (7-isopropoxy-isoflavone)</i>
4.	<i>Ipriflavone (7-isopropoxy-isoflavone)</i>
5.	<i>Ipriflavone (7-isopropoxy-isoflavone)</i>
6.	<i>Ipriflavone (7-isopropoxy-isoflavone)</i>
7.	<i>Ipriflavone (7-isopropoxy-isoflavone)</i>

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Ipriflavone

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>Ipriflavone</i>	<i>Printed Box – 42 Capsules Label – 42 Capsules</i>
2.	<i>Ipriflavone</i>	<i>Printed Box – 42 Capsules Label – 42 Capsules</i>
3.	<i>Ipriflavone</i>	<i>Printed Box – 42 Capsules Label – 42 Capsules</i>
4.	<i>Ipriflavone</i>	<i>Printed Box – 42 Capsules Label – 42 Capsules</i>
5.	<i>Ipriflavone</i>	<i>Printed Box – 42 Capsules</i>
6.	<i>Ipriflavone</i>	<i>Printed Box – 42 Capsules</i>
7.	<i>Ipriflavone</i>	<i>Printed Box – 42 Capsules Label – 42 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: 12.1.98

By: *Patricia L. Vazquez*

Title: *Director, Regulatory Affairs*