



SEP - 8 2000

5 6 3 2 '00 OCT -3 P2:33

Ms. Nancy C. Graves
Quality Manager
Natural Balance, Inc.
3155 N. Commerce Court
Castle Rock, Colorado 80104

Dear Ms. Graves:

This is in response to your letter to the Food and Drug Administration (FDA), dated August 28, 2000, 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 Natural Balance, Inc. is making the following claims for the products below:

Super Flex® Joint Formula

- "...reduce joint pain..."
- "...reduces inflammation, repairs joint and muscle tissue and restores the condition of cartilage between joints"
- "...reduce painful joint and muscle inflammation as well as restore healthy connective tissue"
- "...inhibit the COX-2 enzyme, responsible for back inflammation"
- "...natural way to reduce joint pain so you can enjoy life to the fullest with more range of movement and flexibility"
- "...reduce inflammation, soreness and stiffness"
- "...get you back in the game so you can engage in activities all day with less pain"
- "...inhibits the COX-2 enzyme, responsible for painful joint and muscle inflammation..."

No More Aching Joints!™

- "...reduce joint pain, increase mobility and improve flexibility"
- "...reduces inflammation, and helps improve the condition of joint and muscle tissue"
- "...reduce painful joint and muscle inflammation as well as restore healthy connective tissue"
- "...inhibit the COX-2 enzyme responsible for back inflammation"
- "Proven to reduce inflammation"
- "...natural way to reduce joint pain so you can enjoy life to the fullest with more range of movement and flexibility"
- "...reduce inflammation, soreness and stiffness"
- "...inhibits the COX-2 enzyme, responsible for painful joint and muscle inflammation..."

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Page 2 - Ms. Nancy C. Graves

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 these products, including the name of the product **No More Aching Joints!**TM, suggests that they are intended to treat, prevent, or mitigate a disease, namely inflammatory joint, back, and muscle disorders. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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

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 Office, Compliance Branch, HFR-SW240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-811 (r/f, file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz)
GCF-1 (Barnett, Nickerson, Dorsey)
f/t:rjm:HFS-811:8/6/00:72247.adv:disc50



August 25, 2000

RECEIVED
AUG 31 2000
BY:

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

Dear Sirs,

I am enclosing written notification for the following Natural Balance product whose labeling includes one or more of the statements listed in section 403r (6) of the Federal Food, Drug and Cosmetic Act.

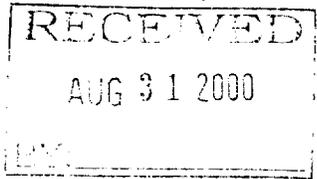
- 1) Super Flex ® Joint Formula

Please contact me if you have any questions, or need additional information. Thank you.

Sincerely,

Nancy C Graves
Nancy C Graves
Quality Manager

Enclosure



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

This notification is being filed on behalf of Natural Balance, Inc., 3155 N. Commerce Court, Castle Rock, CO 80104, 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 Super Flex® Joint Formula.

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

- Statement 1: Super Flex® Joint Formula *Offers you a natural way to reduce joint pain, increase mobility and improve flexibility.*
- Statement 2: Super Flex® Joint Formula, *used as directed, reduces inflammation, repairs joint and muscle tissue and restores the condition of cartilage between joints.*
- Statement 3: Super Flex® Joint Formula *offers you a potent blend of natural ingredients known to reduce painful joint and muscle inflammation as well as restore healthy connective tissue.*
- Statement 4: Super Flex® Joint Formula *can help improve mobility and flexibility so you can enjoy healthful activities again.*
- Statement 5: *Turmeric and Ginger. Important phytonutrients that inhibit the COX-2 enzyme, responsible for back inflammation.*
- Statement 6: *Trans-resveratrol. Powerful, phytonutrient that helps reverse free-radical damage to vertebra tissue and helps inhibit COX-2.*
- Statement 7: *Glucosamine. Known to restore connective tissue and maintain synovial fluid in vertebra tissue.*
- Statement 8: *MSM (methylsulfonylmethane). Helps connective tissue absorb fluid to cushion the shock of movement and activity.*
- Statement 9: Super Flex® Joint Formula *offers you a natural way to reduce joint pain so you can enjoy life to the fullest with more range of movement and flexibility.*
- Statement 10: *This exclusive formula provides you with the most effective natural ingredients known to reduce inflammation, soreness and stiffness.*
- Statement 11: *When used as directed, Super Flex® Joint Formula will get you back in the game so you can engage in activities all day with less pain.*
- Statement 12: *This advanced formula includes a special blend of ingredients that actually inhibits the COX-2 enzyme, responsible for painful joint and muscle inflammation, including knees, hips, wrists, elbows, neck, shoulders, hands and feet.*
- Statement 13: *The comprehensive Super Flex® Joint Formula blend contains Glucosamine, a natural compound that helps repair and restore connective tissue, including cartilage, tendons and ligaments.*

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NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA AND 21 C.F.R. § 101.93
Super Flex® Joint Formula

- Statement 14: *Studies show that Glucosamine assists your body's own repair mechanism by promoting the production of collagen, a protein that holds connective tissue together.*
- Statement 15: *Studies show that MSM actually binds water in the cartilage matrix, keeping cartilage between joints soft and spongy so it absorbs the wear-and-tear of movement and activity.*

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>Vitamin C, Glucosamine, MSM, Boswellin, Ginger, Turmeric, Protykin trans-Resveratrol</i>
2.	<i>Vitamin C, Glucosamine, MSM, Boswellin, Ginger, Turmeric, Protykin trans-Resveratrol</i>
3.	<i>Vitamin C, Glucosamine, MSM, Boswellin, Ginger, Turmeric, Protykin trans-Resveratrol</i>
4.	<i>Vitamin C, Glucosamine, MSM, Boswellin, Ginger, Turmeric, Protykin trans-Resveratrol</i>
5.	<i>Turmeric, Ginger</i>
6.	<i>Protykin trans-Resveratrol</i>
7.	<i>Glucosamine</i>
8.	<i>MSM</i>
9.	<i>Glucosamine, MSM, Boswellin, Ginger, Turmeric, Protykin trans-Resveratrol</i>
10.	<i>Vitamin C, Glucosamine, MSM, Boswellin, Ginger, Turmeric, Protykin trans-Resveratrol</i>
11.	<i>Vitamin C, Glucosamine, MSM, Boswellin, Ginger, Turmeric, Protykin trans-Resveratrol</i>
12.	<i>Turmeric, Ginger, Protykin trans-Resveratrol</i>
13.	<i>Glucosamine</i>
14.	<i>Glucosamine</i>
15.	<i>MSM</i>

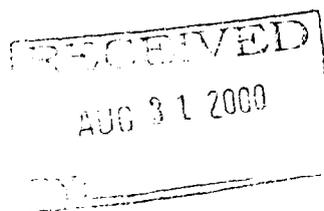
Super Flex® Joint Formula

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.	Super Flex® Joint Formula	<i>Printed Box - 60 Tablets Label - 60 Tablets</i>
2.	Super Flex® Joint Formula	<i>Printed Box - 60 Tablets Label - 60 Tablets</i>
3.	Super Flex® Joint Formula	<i>Printed Box - 60 Tablets Label - 60 Tablets</i>
4.	Super Flex® Joint Formula	<i>Printed Box - 60 Tablets Label - 60 Tablets</i>
5.	Super Flex® Joint Formula	<i>Printed Box - 60 Tablets Label - 60</i>
6.	Super Flex® Joint Formula	<i>Printed Box - 60 Tablets Label - 60 Tablets</i>
7.	Super Flex® Joint Formula	<i>Printed Box - 60 Tablets Label - 60 Tablets</i>
8.	Super Flex® Joint Formula	<i>Printed Box - 60 Tablets Label - 60 Tablets</i>
9.	Super Flex® Joint Formula	<i>Printed Box - 60 Tablets Label - 60 Tablets</i>
10.	Super Flex® Joint Formula	<i>Printed Box - 60 Tablets Label - 60 Tablets</i>
11.	Super Flex® Joint Formula	<i>Printed Box - 60 Tablets Label - 60 Tablets</i>
12.	Super Flex® Joint Formula	<i>Printed Box - 60 Tablets Label - 60 Tablets</i>
13.	Super Flex® Joint Formula	<i>Printed Box - 60 Tablets Label - 60 Tablets</i>
14.	Super Flex® Joint Formula	<i>Printed Box - 60 Tablets Label - 60 Tablets</i>
15.	Super Flex® Joint Formula	<i>Printed Box - 60 Tablets Label - 60 Tablets</i>

I, Nancy C. Graves, 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: 8/28/00 By: NCG
Title: QUALITY MANAGER



August 25, 2000

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

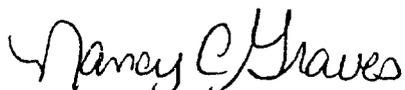
Dear Sirs,

I am enclosing written notification for the following Natural Balance product whose labeling includes one or more of the statements listed in section 403r (6) of the Federal Food, Drug and Cosmetic Act.

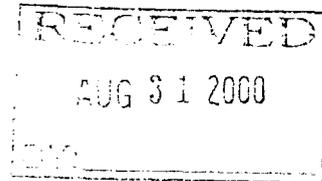
- 1) No More Aching Joints

Please contact me if you have any questions, or need additional information. Thank you.

Sincerely,


Nancy C Graves
Quality Manager

Enclosure



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

This notification is being filed on behalf of Natural Balance, Inc., 3155 N. Commerce Court, Castle Rock, CO 80104, 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
No More Aching Joints!™

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

- Statement 1: *No More Aching Joints! offers you a natural way to reduce joint pain, increase mobility and improve flexibility.*
- Statement 2: *When used as directed, No More Aching Joints! reduces inflammation, and helps improve the condition of joint and muscle tissue.*
- Statement 3: *No More Aching Joints! offers you a potent blend of natural ingredients known to reduce painful joint and muscle inflammation as well as restore healthy connective tissue.*
- Statement 4: *No More Aching Joints! can help improve mobility and flexibility so you can enjoy healthful activities again.*
- Statement 5: *Turmeric and Ginger. Important phytonutrients that inhibit the COX-2 enzyme responsible for back inflammation.*
- Statement 6: *Trans-Resveratrol. Powerful, phytonutrient that helps reverse free-radical damage to vertebra tissue and helps inhibit COX-2.*
- Statement 7: *Boswellin. Proven to reduce inflammation.*
- Statement 8: *Glucosamine. Known to restore connective tissue and maintain synovial fluid in vertebra tissue.*
- Statement 9: *MSM (methylsulfonylmethane). Helps connective tissue absorb fluid to cushion the shock of movement and activity.*
- Statement 10: *No More Aching Joints! offers you a natural way to reduce joint pain so you can enjoy life to the fullest with more range of movement and flexibility.*
- Statement 11: *This exclusive formula provides you with the most effective natural ingredients known to reduce inflammation, soreness and stiffness.*
- Statement 12: *When used as directed No More Aching Joints! will get you back in the game so you can engage in activities all day without pain!*
- Statement 13: *This advanced formula includes a special blend of ingredients that actually inhibits the COX-2 enzyme, responsible for painful joint and muscle inflammation, including knees, hips, wrists, elbows, neck, shoulders, hands and feet.*
- Statement 14: *The comprehensive No More Aching Joints! blend contains Glucosamine, a natural compound that helps repair and restore connective tissue, including cartilage, tendons and ligaments.*

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NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA AND 21 C.F.R. § 101.93
 No More Aching Joints!™

Statement 15: *Studies show that Glucosamine assists your body's own repair mechanism by promoting the production of collagen, a protein that holds connective tissue together.*

Statement 16: *Studies show that MSM actually binds water in the cartilage matrix, keeping cartilage between joints soft and spongy so it absorbs the wear-and-tear of movement and activity.*

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>Vitamin C, Glucosamine, MSM, Boswellin, Ginger, Turmeric, Protykin Trans-resveratrol</i>
2.	<i>Vitamin C, Glucosamine, MSM, Boswellin, Ginger, Turmeric, Protykin Trans-resveratrol</i>
3.	<i>Vitamin C, Glucosamine, MSM, Boswellin, Ginger, Turmeric, Protykin Trans-resveratrol</i>
4.	<i>Vitamin C, Glucosamine, MSM, Boswellin, Ginger, Turmeric, Protykin Trans-resveratrol</i>
5.	<i>Turmeric, Ginger</i>
6.	<i>Protykin Trans-resveratrol</i>
7.	<i>Boswellin</i>
8.	<i>Glucosamine</i>
9.	<i>MSM</i>
10.	<i>Vitamin C, Glucosamine, MSM, Boswellin, Ginger, Turmeric, Protykin Trans-resveratrol</i>
11.	<i>Vitamin C, Glucosamine, MSM, Boswellin, Ginger, Turmeric, Protykin Trans-resveratrol</i>
12.	<i>Vitamin C, Glucosamine, MSM, Boswellin, Ginger, Turmeric, Protykin Trans-resveratrol</i>
13.	<i>Protykin Trans-resveratrol, Turmeric & Ginger</i>
14.	<i>Glucosamine</i>
15.	<i>Glucosamine</i>
16.	<i>MSM</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.	No More Aching Joints! TM	<i>Printed Box - 48 Tablets Label - 48 Tablets Printed Box - 90 Tablets Label - 90 Tablets</i>
2.	No More Aching Joints! TM	<i>Printed Box - 48 Tablets Label - 48 Tablets Printed Box - 90 Tablets Label - 90 Tablets</i>
3.	No More Aching Joints! TM	<i>Printed Box - 48 Tablets Label - 48 Tablets Printed Box - 90 Tablets Label - 90 Tablets</i>
4.	No More Aching Joints! TM	<i>Printed Box - 48 Tablets Label - 48 Tablets Printed Box - 90 Tablets Label - 90 Tablets</i>
5.	No More Aching Joints! TM	<i>Printed Box - 48 Tablets Label - 48 Tablets Printed Box - 90 Tablets Label - 90 Tablets</i>
6.	No More Aching Joints! TM	<i>Printed Box - 48 Tablets Label - 48 Tablets Printed Box - 90 Tablets Label - 90 Tablets</i>
7.	No More Aching Joints! TM	<i>Printed Box - 48 Tablets Label - 48 Tablets Printed Box - 90 Tablets Label - 90 Tablets</i>
8.	No More Aching Joints! TM	<i>Printed Box - 48 Tablets Label - 48 Tablets Printed Box - 90 Tablets Label - 90 Tablets</i>
9.	No More Aching Joints! TM	<i>Printed Box - 48 Tablets Label - 48 Tablets Printed Box - 90 Tablets Label - 90 Tablets</i>

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

No More Aching Joints!™

- | | | |
|-----|-------------------------|--|
| 10. | No More Aching Joints!™ | <i>Printed Box - 48 Tablets
Label - 48 Tablets
Printed Box - 90 Tablets
Label - 90 Tablets</i> |
| 11. | No More Aching Joints!™ | <i>Printed Box - 48 Tablets
Label - 48 Tablets
Printed Box - 90 Tablets
Label - 90 Tablets</i> |
| 12. | No More Aching Joints!™ | <i>Printed Box - 48 Tablets
Label - 48 Tablets
Printed Box - 90 Tablets
Label - 90 Tablets</i> |
| 13. | No More Aching Joints!™ | <i>Printed Box - 48 Tablets
Label - 48 Tablets
Printed Box - 90 Tablets
Label - 90 Tablets</i> |
| 14. | No More Aching Joints!™ | <i>Printed Box - 48 Tablets
Label - 48 Tablets
Printed Box - 90 Tablets
Label - 90 Tablets</i> |
| 15. | No More Aching Joints!™ | <i>Printed Box - 48 Tablets
Label - 48 Tablets
Printed Box - 90 Tablets
Label - 90 Tablets</i> |
| 16. | No More Aching Joints!™ | <i>Printed Box - 48 Tablets
Label - 48 Tablets
Printed Box - 90 Tablets
Label - 90 Tablets</i> |

I, Nancy C. Graves, 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: 8/28/00 By: Nancy Graves

Title: QUALITY MANAGER