



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

APR 10 2000

Ms. Deborah Shur Trinker
Vice President of Regulatory Affairs
and Assistant General Counsel
Rexall Sundown, Inc.
6111 Broken Sound Parkway, NW
Boca Raton, Florida 33487-3693

Dear Ms. Trinker:

This is in response to your letters of March 15 and March 23, 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 submission states that Rexall Sundown, Inc. is making the following claims, among others, for the following products:

Zinc 30 mg, 50 mg, 100 mg (Sundown)

“...needed for normal wound healing...”

C1000, C1000 with Rose Hips, C1000 “plus” Rose Hips, Bioflavonoids, Rutin and Acerola (Thompson)

“...maintain healthy blood cholesterol levels”

Memory Care™

“Natural aging and poor diet may decrease PS levels resulting in Age-Associated Memory Impairment (AAMI).”

Bilberry (Sundown)

“...reduce capillary fragility and leakage...”

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 suggest that they are intended to treat, prevent, cure or mitigate diseases. 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.

975-0163

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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, Florida District Office, Office of Compliance, HFR-SE240

cc:

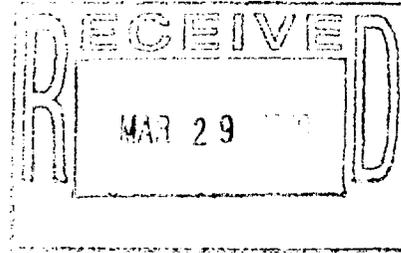
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-811 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Dorsey, Barnett, Nickerson)
f/t:HFS-811:rjm:4/4/00:docname:69996.adv:disc46



6111 Broken Sound Parkway NW
Boca Raton, FL 33487-3693
(561) 241-9400
Fax (561) 995-5188

March 15, 2000

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



Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown, Rexall and SDV brand names bearing the following statement(s) on the label and/or in the labeling:

Bilberry (Sundown): [For] healthy eye function. Bilberry reduces visual fatigue and supports overall eye health. It contains compounds called anthocyanosides that strengthen capillary membranes and reduce capillary fragility and leakage. Bilberry enhances visual acuity by maintaining capillary strength and promoting normal blood flow. British fighter pilots in World War II reported that Bilberry jam enhanced their night vision.

Bilberry Complex (Sundown): [For] healthy eye function. Bilberry reduces visual fatigue and supports overall eye health. It contains compounds called anthocyanosides that strengthen capillary membranes and reduce capillary fragility and leakage. Bilberry enhances visual acuity by maintaining capillary strength and promoting normal blood flow. British fighter pilots in World War II reported that Bilberry jam enhanced their night vision.

Bilberry Extract XTRA (Sundown): [For] healthy eye function. Bilberry reduces visual fatigue and supports overall eye health. It contains compounds called anthocyanosides that strengthen capillary membranes and reduce capillary fragility and leakage caused by oxidative damage associated with aging. Sundown's Bilberry Xtra combines bilberry with other beneficial herbals to enhance visual acuity by maintaining capillary strength and promoting normal blood flow. For a lifetime of healthy vision, protect your eyes with daily use of Sundown's Bilberry Xtra.

Bilberry (Rexall): For healthy eye function. Bilberry has become popular with individuals seeking nutritional support for healthy vision.



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Bilberry Complex (with Ginkgo Biloba, Vitamin A, Vitamin C, Zinc and Carrot Powder) (SDV):
Bilberry Complex provides nutritional support for healthy eye function.

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

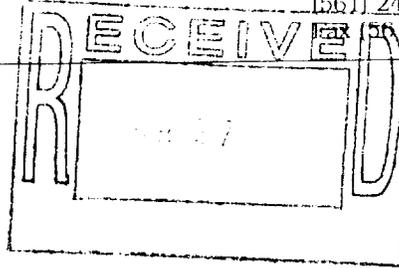


Deborah Shur Trinker
Vice President of Regulatory Affairs
and Assistant General Counsel

Enclosure



6111 Broken Sound Parkway NW
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March 23, 2000

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

Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown brand name bearing the following statement(s) on the label and/or in the labeling:

Memory Care™: [It] promotes healthy brain function and memory. It contains Phosphatidylserine (PS), a naturally occurring nutrient essential to all cells in the body, particularly those in the brain. Natural aging and poor diet may decrease PS levels resulting in Age-Associated Memory Impairment (AAMI). ←

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker
Vice President of Regulatory Affairs
and Assistant General Counsel

Enclosure

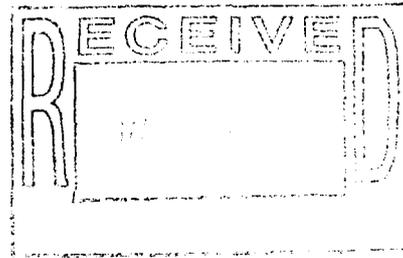
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March 15, 2000

Food and Drug Administration
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Washington, DC 20204



Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Thompson, Sundown, and Rexall brand names bearing the following statement(s) on the label and/or in the labeling:

C Rolla with Natural Rose Hips and Acerola, C250, C250 Plus Natural Rose Hips, Rutin, Hesperidin, Acerola and Bioflavonoids, C500, Super C500, C500 with Natural Rose Hips, C500 Plus Natural Rose Hips, Rutin, Hesperidin, Acerola and Bioflavonoids, C500% Plus Natural Rose Hips, Rutin, Hesperidin, Acerola and Bioflavonoids, C1000, C1000 Plus Natural Rose Hips, Rutin, Hesperidin, Acerola and Bioflavonoids, C1000% Plus Natural Rose Hips, Rutin, Hesperidin, Acerola and Bioflavonoids, C1500, C1500 Plus Natural Rose Hips, Rutin, Hesperidin, Acerola and Bioflavonoids (Sundown): Vitamin C helps promote healthy immune function and general well-being. C acts as an antioxidant to help provide protection for healthy cells and body systems. C is vital to production of collagen, providing the stability necessary for proper cardiovascular function. It is also utilized in the development of the connective tissue in blood vessels, skin, ligaments and bones.

Ester C 500 Plus Natural Rose Hips, Bioflavonoids, Rutin and Acerola (Sundown): [It] promotes healthy immune function and well-being. It acts as an antioxidant to protect cells and body systems. [It] is vital to production and development of connective tissue in blood vessels, skin, ligaments and bones.

C 500mg XTRA (Sundown): For healthy immune function. This Advanced Formula features Vitamin C-500 blended with bioflavonoids, including hesperidin and rutin, as well as minerals Selenium and Zinc. These ingredients work in harmony to promote healthy immune function, capillary strength and provide antioxidant protection for healthy cells, tissues and overall well-being.

C 500 (Thompson): Vitamin C acts as an antioxidant to help provide protection for healthy cells and body systems. Vitamin C helps maintain healthy cardiovascular function.

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C 500, C500 with Rose Hips and Bioflavonoids, C1000 with Rose Hips and Bioflavonoids (Thompson): [It] helps promote healthy immune and cardiovascular function. Vitamin C helps promote healthy immune function and general well-being. Vitamin C acts as an antioxidant to help provide protection for healthy cells and body systems. Vitamin C is vital to production of collagen, providing the stability necessary for proper cardiovascular function. It is utilized in the development of the connective tissue in blood vessels, skin, ligaments and bones. Vitamin C helps maintain healthy cardiovascular function by inhibiting LDL cholesterol oxidation.

Ester-C 500 with Natural Rose Hips, Acerola, Bioflavonoids, Rutin and Hesperidin (Thompson): [It] helps promote healthy immune and cardiovascular function. Vitamin C acts as an antioxidant to help provide protection for healthy cells and body systems. Vitamin C is vital to the production of collagen, providing the stability necessary for proper cardiovascular function. It is also utilized in the development of the connective tissue in blood vessels, skin, ligaments and bones.

C500 (Thompson): [It] helps promote healthy immune function and general well-being. Vitamin C acts as an antioxidant to help provide protection for healthy cells and body systems. Vitamin C is vital to the production of collagen, providing the stability necessary for proper cardiovascular function. It is also utilized in the development of the connective tissue in blood vessels, skin, ligaments and bones.

C1000, C1000 with Rose Hips, C1000 "plus" Rose Hips, Bioflavonoids, Hesperidin, Rutin and Acerola (Thompson): [It] helps promote healthy immune and cardiovascular function. Vitamin C acts as an antioxidant to help provide protection for healthy cells and body systems. Vitamin C is vital to the production of collagen, providing the stability necessary for proper cardiovascular function. It is also utilized in the development of the connective tissue in blood vessels, skin, ligaments and bones. Vitamin C helps maintain healthy blood cholesterol levels. ←

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

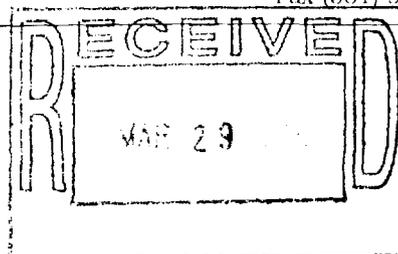


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Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. {"Sundown"} located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown, Thompson and Rexall brand names bearing the following statement(s) on the label and/or in the labeling:

Zinc 30mg, 50mg, 100mg (Sundown): Sundown's Zinc is an essential mineral for healthy immune function and prostate health. It is required for protein synthesis, normal metabolism and healthy cell function. Adequate zinc levels are needed for normal wound healing and maintenance of healthy vision, taste and smell. ←

Zinc Lozenges (Sundown): Sundown's Zinc Lozenges provide a great-tasting combination of Zinc, Vitamin C and Echinacea which promotes healthy immune function. Zinc is a mineral required for protein synthesis and to regulate the production of cells in the body's immune system. It is also necessary for normal metabolism and healthy cell function. Vitamin C and the herb, Echinacea, are added to complement the immune-enhancing effects of zinc.

Zinc 50mg (Thompson): Zinc is an important mineral which is essential for protein synthesis, healthy immune function and prostate health. Zinc is necessary for normal metabolism and helps to maintain healthy cell function. Zinc is also necessary to help maintain the proper concentration of Vitamin E in the blood.

Zinc Lozenge (Thompson)s: [It] helps promote healthy immune function. Thompson Zinc Lozenges provide a select combination of Zinc, Vitamin C and Echinacea which help support and promote healthy immune function. Zinc, an essential mineral, helps to regulate the production of cells in the body's immune system. Zinc is also necessary for normal metabolism and helps to maintain healthy cell function. Vitamin C, a powerful antioxidant, assists with healthy immune system activities. Echinacea is used effectively, worldwide, to promote general well-being.

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