



AUG 21 2000

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R. Elliott Dunn, Jr., Esq.  
General Counsel  
Strictly Supplements, Inc.  
2920 N. Green Valley Parkway  
Bldg. 3, Suite 321  
Henderson, Nevada 89014

Dear Mr. Dunn:

This is in response to your letter of August 9, 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 Strictly Supplements, Inc. is marketing products named **Silvicidal® GS** and **Silvicidal® ND**. These two products are intended to be used as an oral spray that is absorbed from the mouth and as a liquid that is instilled into the nasal passages, respectively. These products do not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, they can not be marketed as dietary supplements.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(I) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the dietary, and are labeled as a dietary supplement.

**Silvicidal® GS** and **Silvicidal® ND** are not products "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976) (defining ingestion as "the taking of material (as food) into the digestive system.")...

975-0163

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The interpretation of the term “ingestion” to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(I) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(I) “only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure.” This elaboration of “liquid form” also denotes ingestion by swallowing the fluid.

Therefore, because the term “ingestion” means introduced into the gastrointestinal tract, products that are absorbed from the mouth prior to ingestion or are administered nasally are not subject to regulation as dietary supplements because they are not “intended for ingestion.”

Please contact us if you require 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, San Francisco District Office, Office of Compliance, HFR-PA140

# **S**trictly Supplements, Inc.

2920 N. Green Valley Parkway, Bldg. 3, Suite 321  
Henderson, NV 89014

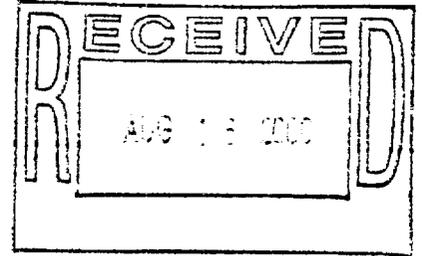
TEL: (702) 547-9009

FAX: (702) 898-7103

August 9, 2000

**Certified Mail - Return Receipt Requested**

Office of Special Nutritionals (HFS-50)  
Center for Food Safety and Applied Nutrition  
200 C Street SW  
Washington, D.C. 20204



**RE: Notice of Use of § 403(r)(6) Statements on Dietary Supplement  
Labels and Labeling**

Gentlemen:

Pursuant to the requirements contained in 21 C.F.R. § 101.93, this is to notify your office of the following information with respect to four dietary supplements distributed by Strictly Supplements, Inc., 2920 N. Green Valley Parkway, Building 3, Suite 321, Henderson, Nevada 89014 (formerly located at 3733 Howard Hughes Parkway, 290N, Las Vegas, Nevada 89109). The names of the dietary supplements, and the text of the statements used on or in the label or labeling of the products, are as follows:

1. Silvicidal® GS - "Natural Mineral Immune Energizer" and "... effective in energizing the human body's natural immune system."
2. Silvicidal® ND - "Natural Mineral Immune Energizer" and "... helps to energize the human body's natural immune system."
3. Silvicidal® 350 - "An All Natural Mineral Immune Energizer" and "... helps energize the human body's natural immune system."
4. CellStat™ - "Helps Maintain Normal Cell Function", "helps maintain the normal function of the cells in the human body" and "To help maintain the normal cell function in the human body take one capsule daily."

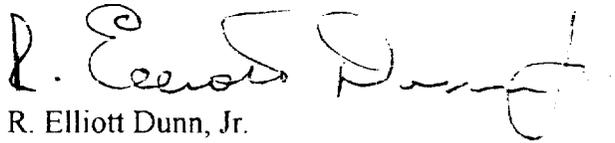
Office of Special Nutritionals

August 9, 2000

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Photocopies of the labels and labeling for each of these supplements are included with this notice. The undersigned certifies that Strictly Supplements, Inc. has information to substantiate that the statements made are truthful and are not misleading, and that the information contained herein is accurate and complete.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Elliott Dunn, Jr.", written in a cursive style.

R. Elliott Dunn, Jr.  
General Counsel

Enclosures: (4)

# SILVICIDAL® GS

## Natural Mineral Immune Energizer\*

**GENERAL INFORMATION:** Silvicidal® GS is a safe, natural mineral product, which should be used for its value as a mineral nutrient supplement to the human diet. It has been found to be effective in energizing the human body's natural immune system.\* However, due to differences in metabolism between individuals, this product may not be effective for all people. If the product does not appear to be effective for a particular user, then its use should be discontinued. The user should not exceed the recommended daily amount. As is true with certain other products, more is not necessarily better.

**USE:** Silvicidal® GS is in a liquid form that is designed to be introduced into the body by spraying it into the open mouth, where it will be absorbed. It may be used up to 3 times per day. To allow for complete absorption, the user should not drink any liquid, or rinse the mouth, for at least 30 minutes after use.

**STORAGE:** Store at room temperature, out of direct sunlight, in original tube container.

**WARNINGS:** There are no known adverse side effects from the use of Silvicidal® GS, as none have been reported by any user of the product. Toxicity studies done on animals using extremely high concentrations have not produced any adverse side effects. Although no side effects have been reported, side effects could occur, and if the user feels that some side effect has occurred from the use of this product, the user should contact their physician immediately.

There is scientific evidence that the use of citric acid may cause certain products ingested to cross the blood brain barrier. Therefore, to avoid this possibility, unless authorized or prescribed by physician, it is best to avoid citric acid products (like orange or grapefruit juice) within one half hour both before or after ingesting any dietary supplement or medication.

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Manufactured by:

Strictly Supplements, Inc.  
2920 N. Green Valley Parkway  
Building 3  
Henderson, NV 89014

Henderson, NV 89014  
Tel: (702) 547-9009

SUPPLEMENT FACTS	
Serving Size 1 Spray Servings Per Container 180	
Amount Per Serving	% Daily Value
Proprietary Blend 22.8mcg	**
Silver	**
MSM	**
Distilled Deionized Water	**

\*\*Daily Value not established

Expiration Date:

Lot #

# Silvicidal® GS

Dietary Supplement with Spray Applicator

NATURAL MINERAL IMMUNE ENERGIZER\*



READ PACKAGE INSERT  
BEFORE USING THIS PRODUCT  
Contents: 1 Fluid Ounce

\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.

**DIRECTIONS:** Spray into open mouth. Wait 30 minutes before drinking liquids or rinsing mouth to allow for complete absorption.

**STORAGE:** Store bottle in original tube container at room temperature.

**WARNINGS:** There are no known adverse side effects of this product, but if pregnant or nursing, consult a physician before using. Keep out of the reach of children. Do not use if seal is broken on tube container.

Manufactured by:

Strictly Supplements, Inc.  
2920 N Green Valley Parkway  
Building 3  
Henderson, Nevada 89014

SUPPLEMENT FACTS	
Serving Size 1 Spray Servings Per Container 180	
Amount Per Serving	% Daily Value
Proprietary Blend 22.8mcg	**
Silver	**
MSM	**
Distilled Deionized Water	**

\*\* Daily value not established

Expiration Date

Lot #

## Silvicidal® GS

Dietary Supplement with Spray Applicator

NATURAL MINERAL IMMUNE ENERGIZER\*

READ PACKAGE INSERT BEFORE USING THIS PRODUCT  
Contents: 1 Fluid Ounce

\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.

**DIRECTIONS FOR USE:** Spray into open mouth. Wait 30 minutes before drinking liquids or rinsing mouth to allow for complete absorption.

**STORAGE:** Store in original tube container at room temperature.

**WARNINGS:** There are no known adverse side effects of this product, but if pregnant or nursing, consult a physician before using. Keep out of the reach of children. Do not use if seal is broken on tube container.

Manufactured by:  
Strictly Supplements, Inc.  
2920 N Green Valley Parkway  
Building 3  
Henderson, NV 89014

# SILVICIDAL® ND

## Natural Mineral Immune Energizer\*

**GENERAL INFORMATION:** Silvicidal® ND is a safe, natural mineral product, which should be used for its value as a mineral nutrient supplement to the human diet. It has been found that Silvicidal® ND helps to energize the human body's natural immune system. \* However, due to differences in metabolism between individuals, this product may not be effective for all people. If the product does not appear to be effective for a particular user, then its use should be discontinued. The user should not exceed the recommended daily amount. As is true with certain other products, "more is not necessarily better".

**USE:** Silvicidal® ND is in a liquid form that is designed to be introduced into the body by putting drops into each nostril where it will be absorbed. Use 1 drop in each nostril up to 3 times per day.

**STORAGE:** Store at room temperature, out of direct sunlight, in original tube container.

**WARNINGS:** There are no known adverse side effects from the use of Silvicidal® ND, as none have been reported by any user of the product. Toxicity studies done on animals using extremely high concentrations have not produced any adverse side effects. Although no side effects have been reported, side effects could occur, and if the user feels that some side effect has occurred from the use of this product, the user should contact their physician immediately.

There is scientific evidence that the use of citric acid may cause certain products ingested to cross the blood brain barrier. Therefore, to avoid this possibility, unless authorized or prescribed by physician, it is best to avoid citric acid products (like orange or grapefruit juice) within one half hour both before or after ingesting any dietary supplement or medication.

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Manufactured by:

Strictly Supplements, Inc.  
2920 N. Green Valley Parkway  
Building 3  
Henderson, NV 89014  
Tel: (702) 547-9009

SUPPLEMENT FACTS	
Serving Size 1 drop per nostril Servings Per Container 750	
Amount Per Serving	% Daily Value
Proprietary Blend .75mcg	**
Silver	**
Distilled Deionized Water	**
**Daily Value not established	
Expiration Date:	
Lot #	

# Silvicidal® ND

Dietary Supplement with Dropper

## NATURAL MINERAL IMMUNE ENERGIZER\*



READ PACKAGE INSERT BEFORE USING THIS PRODUCT

Contents: 1 Fluid Ounce

\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.

**DIRECTIONS:** With head tilted backward, using enclosed dropper, place one to three drops in each nostril, up to 3 times per day.

**STORAGE:** Store in original tube container at room temperature.

**WARNINGS:** There are no known adverse side effects of this product, but if pregnant or nursing, consult a physician before using. Keep out of the reach of children. Do not use if seal is broken on tube container.

Manufactured by:  
Strictly Supplements, Inc.  
2920 N Green Valley Parkway  
Building 3  
Henderson, Nevada 89014

SUPPLEMENT FACTS	
Serving Size 1 drop per nostril Servings Per Container 750	
Amount Per Serving	% Daily Value
Proprietary Blend .75mcg	**
Silver	**
Distilled Deionized Water	**
** Daily value not established	
Expiration Date	
Lot #	

# Silvicidal® ND

Dietary Supplement with Dropper

## NATURAL MINERAL IMMUNE ENERGIZER\*

READ PACKAGE INSERT BEFORE USING THIS PRODUCT

Contents: 1 Fluid Ounce

\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.

**DIRECTIONS FOR USE:** With head tilted backward, using enclosed dropper, place one to three drops in each nostril, up to 3 times per day.

**STORAGE:** Store in original tube container at room temperature.

**WARNINGS:** There are no known adverse side effects of this product, but if pregnant or nursing, consult a physician before using. Keep out of the reach of children. Do not use if seal is broken on tube container.

Manufactured by:  
Strictly Supplements, Inc.  
2920 N Green Valley Parkway  
Building 3  
Henderson, Nevada 89014

# SILVICIDAL® 350

## An All Natural Mineral Immune Energizer\*

**GENERAL INFORMATION:** Silvicidal® 350 is a safe, natural mineral product, which should be used for its value as a mineral nutrient supplement to the human diet. It has been found that Silvicidal® 350 helps energize the human body's natural immune system.\* However, due to differences in metabolism between individuals, this product may not be effective for all people. If the product does not appear to be effective for a particular user, then its use should be discontinued. The user should not exceed the recommended daily amount. As is true with certain other products, \*more is not necessarily better.

**USE:** Silvicidal® 350 is in a liquid form that can be taken by mouth once per day. Pour 1/8 ounce into the enclosed measuring cup and fill cup to 3/4 ounce line with water.

**STORAGE:** Store at room temperature, out of direct sunlight, in original tube container.

**WARNINGS:** There are no known adverse side effects from the use of Silvicidal® 350, as none have been reported by any user of the product. Toxicity studies done on animals using extremely high concentrations have not produced any adverse side effects. Although no side effects have been reported, side effects could occur, and if the user feels that some side effect has occurred from the use of this product, the user should contact their physician immediately.

There is scientific evidence that the use of citric acid may cause certain products ingested to cross the blood brain barrier. Therefore, to avoid this possibility, unless authorized or prescribed by physician, it is best to avoid citric acid products (like orange or grapefruit juice) within one half hour before or after ingesting any dietary supplement or medication.

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Manufactured by:

**Strictly Supplements, Inc.**  
 2920 N. Green Valley Parkway  
 Building 3  
 Henderson, NV 89104  
 Tel: (702) 547-9009

### SUPPLEMENT FACTS

Serving Size 1/8 ounce  
 Servings Per Container 32

Amount Per Serving	% Daily Value
Proprietary Blend 196mcg	**
Silver	**
Distilled Deionized Water	**

\*\* Daily value not established

**Silvicidal®  
 350**  
 DIETARY SUPPLEMENT

**AN ALL NATURAL  
 MINERAL IMMUNE ENERGIZER\***



Contents: 4 Fluid Ounces

\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.

**DIRECTIONS:** Once daily, put 1/8 ounce of Silvicidal 350 into enclosed measuring cup and fill to 3/4 ounce line with water.

**STORAGE:** Store at room temperature in original tube container.

**WARNINGS:** Adult use only. Keep out of reach of children. Do not use if seal is broken on tube container.

Manufactured by:  
**Strictly Supplements, Inc.**  
 2920 Green Valley Pkwy., Bldg. 3  
 Henderson, NV 89014

Exp. Date:

Lot #

**CellStat™**

**Helps Maintain Normal Cell Function\***

**GENERAL INFORMATION**

CellStat contains *trans-Resveratrol*, which is a natural product derived from grapes. It has been found that *trans-Resveratrol*, acting in several different ways upon certain bodily chemistry, helps maintain the normal function of the cells in the human body.\*

**USE:** To help maintain the normal cell function in the human body take one capsule daily.\*

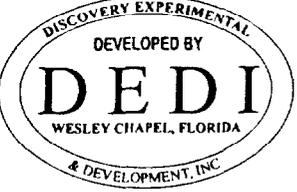
**STORAGE:** Store in the original tube container at room temperature.

**WARNINGS:** Use only as directed. Keep out of the reach of children. Do not use if you are taking prescription medication, are pregnant or nursing a baby unless directed by a physician.

\* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Manufactured by:

**Strictly Supplements, Inc.**  
 2920 N Green Valley Parkway  
 Building 3  
 Henderson, NV 89104  
 Tel: (702) 547-9009

<p><b>SUPPLEMENT FACTS</b>          Serving Size 1 capsule          Servings Per Container 60</p> <table border="1"> <thead> <tr> <th>Amount Per Serving</th> <th>% Daily Value</th> </tr> </thead> <tbody> <tr> <td>Proprietary Blend 5mg</td> <td>**</td> </tr> <tr> <td>Avicel</td> <td>**</td> </tr> <tr> <td>Isolate of Knotweed</td> <td>**</td> </tr> </tbody> </table> <p>** Daily Value not established</p>	Amount Per Serving	% Daily Value	Proprietary Blend 5mg	**	Avicel	**	Isolate of Knotweed	**	<p><b>CellStat™</b>          DIETARY SUPPLEMENT  <i>trans-Resveratrol</i>  <b>HELPS MAINTAIN NORMAL CELL FUNCTION*</b></p> 	<p><b>DIRECTIONS:</b> Take 1 capsule daily.  <b>STORAGE:</b> Store in original tube container at room temperature.  <b>WARNINGS:</b> Adult use only. Keep out of the reach of children.</p>
Amount Per Serving	% Daily Value									
Proprietary Blend 5mg	**									
Avicel	**									
Isolate of Knotweed	**									
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Amount Per Serving	% Daily Value									
Proprietary Blend 5mg	**									
Avicel	**									
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