

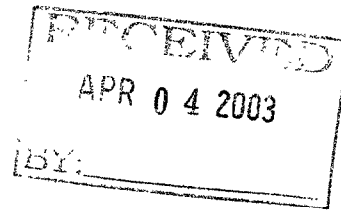
A.G. WATERHOUSE, LLC

1210 S Walnut, Casper, Wyoming 82401 '03 APR 15 P1:57

March 24, 2003

VIA CERTIFIED MAIL

Food and Drug Administration
200 C Street S.W.
Washington, DC 20204



RE: Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93

Dear Sir or Madam:

Enclosed please find the Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93 for the dietary supplement product Leptoprin™. This notification is on behalf of A.G. Waterhouse, LLC.

Please review the information at your earliest convenience. Please contact me at 801-517-7047 with any questions of if there is any further information I can provide regarding this matter.

Sincerely,

A handwritten signature in cursive script that reads "Kristen Jones".

Kristen Jones
Admin. Assistant

/encls.

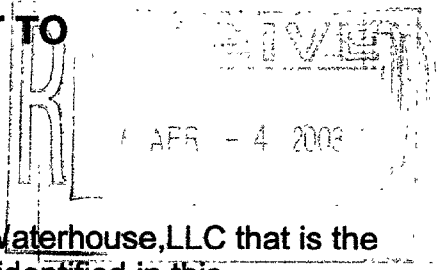
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8-3995

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR § 101.93**



This notification is being filed on behalf of A.G. Waterhouse, LLC that is the Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 1210 S Walnut, Casper, Wyoming 82601. 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 the statements appear is **Leptoprin™**.

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

- (Statement 1): "Acute Metabolic Regulator"
- (Statement 2): "Weight Control Compound for The Significantly Overweight"

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the Subject of the Statement:</u>
1	Leptoprin™--180ct bottle
2	Leptoprin™--180ct bottle

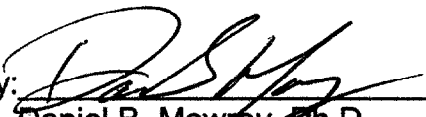
The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	A.G. Waterhouse, LLC	both
2	A.G. Waterhouse, LLC	both

82,995

I, Daniel B. Mowrey, Ph.D., am authorized to certify this Notification on behalf of A.G. Waterhouse, LLC. I certify that the information presented and contained in this Notification is complete and accurate, and that A.G. Waterhouse, LLC has substantiation that each structure-function statement is truthful and not misleading.

Dated this 21st day of March, 2003.

By: 
Daniel B. Mowrey, Ph.D.
Consultant to A.G. Waterhouse, LLC

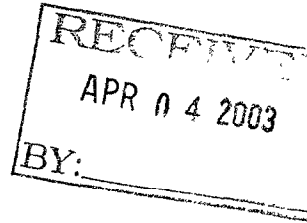
A.G. WATERHOUSE, LLC

1210 S Walnut, Casper, Wyoming 82601

March 24, 2003

VIA CERTIFIED MAIL

Food and Drug Administration
200 C Street S.W.
Washington, DC 20204



RE: Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93

Dear Sir or Madam:

Enclosed please find the Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93 for the dietary supplement product Leptoprin-SF™. This notification is on behalf of A.G. Waterhouse, LLC.

Please review the information at your earliest convenience. Please contact me at 801-517-7047 with any questions of if there is any further information I can provide regarding this matter.

Sincerely,

A handwritten signature in cursive script that reads "Kristen Jones".

Kristen Jones
Admin. Assistant

/encls.

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR § 101.93**

This notification is being filed on behalf of A.G. Waterhouse, LLC that is the Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 1210 S Walnut, Casper, Wyoming 82601. 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 the statements appear is **Leptoprin-SF™**.

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

- (Statement 1): "Acute Metabolic Regulator"
 (Statement 2): "Weight Control Compound for The Significantly Overweight"

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

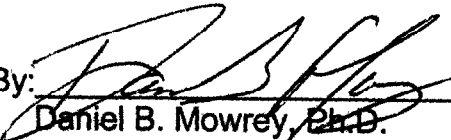
<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the Subject of the Statement:</u>
1	Leptoprin-SF™--180ct bottle
2	Leptoprin-SF™--180ct bottle

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	A.G. Waterhouse, LLC	both
2	A.G. Waterhouse, LLC	both

I, Daniel B. Mowrey, Ph.D., am authorized to certify this Notification on behalf of A.G. Waterhouse, LLC. I certify that the information presented and contained in this Notification is complete and accurate, and that A.G. Waterhouse, LLC has substantiation that each structure-function statement is truthful and not misleading.

Dated this 21st day of March, 2003.

By: 
Daniel B. Mowrey, Ph.D.
Consultant to A.G. Waterhouse, LLC

AC WATERHOUSE

Distributed by A.G. Waterhouse™

The recommended serving is two capsules three times a day, which is the exact serving used in the clinical trials. However, many people who are sensitive to stimulants have reduced the serving as low as one capsule twice a day and have still seen results. As with many ingestible compounds, each individual reacts differently to Leptoprin. The effective serving depends upon a person's body weight, metabolism, and overall health. You may want to start with one Leptoprin capsule twice a day and gradually increase the serving (up to the recommended level) until you find what works best for your body.

*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.

If you experience adverse effects after consumption of this product and you live in Texas, please call 1-800-332-1088. If you live outside of Texas, call your local Poison Control Center; or, if an emergency call 911. For any other product information, call customer service at 1-800-898-5153.

WARNING: Do not take this product with any other product containing Ephedrine, Ephedra, or Ma Huang.

WARNING: Maximum recommended total amount of ephedrine for a healthy adult human is no more than 100mg in a 24-hour period for not more than 12 weeks. Improper use of the product may be hazardous to a person's health.

Use only as directed. Store at controlled room temperature 15°-30°C/59°-86°F
Produced under exclusive license: U.S. Patent Nos. 5,019,594 and 5,055,460

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BR214

MFS 12635-10BK9-70

LEPTOPRIN™

(Acute Metabolic Regulator*)

**Weight Control Compound For
The Significantly Overweight***

Notice: Before starting this or any weight-control program, check with your health-care provider to make sure you are in overall good health. If your health-care provider has any questions regarding Leptoprin, please have him or her call 1-800-898-5153.

**Not to be used as
a casual diet-aid**

180 capsules

Dietary Supplement

AC WATERHOUSE Distributed by A.G. Waterhouse™

Active Ingredients: Acetylsalicylic Acid, Caffeine, Ephedrine Alkaloids

Supplement Facts

Serving Size: 2 capsules
Servings Per Container: 90

	Amount Per Serving	% Daily Value*
Vitamin B6	25mg	1250%
Calcium (as calcium amino acid chelate)	48mg	5%
Leptoprin™ A proprietary blend of the following:	849mg	
Acetylsalicylic acid	324mg	†
Caffeine (34mg from standardized Kola nut [280mg])	200mg	†
Green Tea (leaf) Extract (standardized for polyphenols/ catechins content)		†
L-Tyrosine		†
Kelp (0.15% Iodine [100mg])		†
Ephedrine alkaloids (exclusive 10% extract from Whole Plant Ma Huang [200mg])	20mg	†
Cayenne (fruit)		†

* Percent Daily Values are based on a 2,000 calorie diet
† Daily Value not established

Other Ingredients: rice flour

Distributed by: A.G. Waterhouse™
Casper, WY 82601 • 1-800-898-5153
Made in the U.S.A.

www.Leptoprin.com

Leptoprin Directions: Take two capsules with a full glass of water, three times per day: morning, noon, and early evening. You may take Leptoprin with or without food. Do not exceed 6 capsules per day.

Note: Jitters, anxiety, dry mouth, or insomnia may occur during the first week of use. Reducing number of capsules per day during the first week should eliminate these mild effects. For additional information on this or any other A.G. Waterhouse product, please call our experienced customer service representatives at 1-800-898-5153.

WARNINGS: Before using this product consult your health-care provider. Do not take if sensitive to or if allergic to aspirin. Do not use if pregnant (it is especially important not to use aspirin during the last 3 months of pregnancy unless specifically directed to do so by a physician because it may cause problems in the unborn child or complications during delivery), nursing, have asthma, or have stomach problems (such as heartburn, upset stomach or stomach pain) that persist or recur, or if you have ulcers or bleeding problems, unless directed by a physician. Do not use if you are susceptible to ephedra psychosis. If ringing in the ears or temporary loss of hearing occurs, consult a physician before taking again.

DRUG INTERACTION PRECAUTION: Do not take this product if you are taking MAO inhibitors or a prescription drug for anticoagulation (thinning of the blood), diabetes, gout or arthritis, or any other prescription drug unless directed by a physician. Do not take this product if you have any of the following conditions: high blood pressure, cardiovascular disease, thyroid disease, prostate problems, or diabetes. This product is not intended for pain relief, fever, toothache, or any other analgesic effect.

Keep out of the reach of children. Children and teenagers should not use this product, or any other product containing aspirin, for chicken pox or flu symptoms before a physician is consulted about Reye Syndrome, a rare but serious illness reported to be associated with aspirin. In case of overdose, get medical help or contact a Poison Control Center right away.

WARNING: Not for use by individuals under the age of 18. Do not use if pregnant or nursing. Consult a physician or licensed qualified health-care professional before using this product if you have, or have a family history of, heart disease, thyroid disease, diabetes, high blood pressure, recurrent headaches, depression or other psychiatric condition, glaucoma, difficulty in urinating, prostate enlargement, or seizure disorder, or if you are using a monoamine oxidase inhibitor (MAOI) or any other dietary supplement, prescription drug or over-the-counter drug containing ephedrine, pseudoephedrine or phenylpropanolamine (ingredients found in certain allergy, asthma, cough/cold, and weight-control products). Exceeding recommended serving may cause serious adverse health effects including heart attack and stroke. This product has 20 milligrams concentrated ephedrine group alkaloids per serving in the form of herbal extracts and may cause serious adverse health effects.

Read the label and follow directions. Discontinue use and call a physician or licensed health-care professional immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath, or other similar symptoms. Consumption in excess of the recommended servings, or consumption of a serving at a more frequent interval than recommended, may cause adverse health effects, including heart attack and stroke. Individuals who consume caffeine with this product may experience serious adverse health effects.

ALCOHOL WARNING: If you consume 3 or more alcoholic drinks every day, ask your physician whether you should take aspirin. Aspirin may cause stomach bleeding.

AC WATERHOUSE Distributed by A.G. Waterhouse™

AC WATERHOUSE

Distributed by A.G. Waterhouse™

MFS 12635-10BK9-72

LEPTOPRIN-SF™
(Acute Metabolic Regulator*)

STIMULANT-FREE

**Weight Control Compound For
The Significantly Overweight***

Notice: Before starting this or any weight-control program, check with your health-care provider to make sure you are in overall good health. If your health-care provider has any questions regarding Leptoprin-SF, please have him or her call 1-800-898-5153.

Use only as directed. Store at controlled room temperature 15°-30°C/59°-86°F

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Not to be used as a casual diet-aid

**180 capsules
Dietary Supplement**

AC WATERHOUSE Distributed by A.G. Waterhouse™

Supplement Facts

Serving Size: 2 capsules
Servings Per Container: 90

	Amount Per Serving	% Daily Value*
Calcium (as calcium amino acid chelate)	24mg	2.5%
Leptoprin-SF™	1.5gm	
A proprietary blend of the following:		
Calcium phosphate		†
Commiphora mukul extract		†
Garcinia cambogia (HCA 125mg)		†
L-Tyrosine		†
Acetylsalicylic acid	162.5mg	†
Dipotassium phosphate		†
Sodium phosphate		†
Disodium phosphate		†
Phosphatidyl choline		†
Scutellaria (root)		†
Bupleurum (root)		†
Epimedium (entire plant)		†

* Percent Daily Values are based on a 2,000 calorie diet
† Daily Value not established

Other Ingredients: rice flour

Distributed by:

A.G. Waterhouse™

Casper, WY 82601 • 1-800-898-5153

Made in the U.S.A.

www.Leptoprin.com

Leptoprin-SF Directions: Take two capsules with a full glass of water, three times per day: morning, noon, and early evening. You may take Leptoprin-SF with or without food. Do not exceed recommended use.

*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.

WARNINGS: Do not take if sensitive to or if allergic to aspirin. Do not use if pregnant (it is especially important not to use aspirin during the last 3 months of pregnancy unless specifically directed to do so by a physician because it may cause problems in the unborn child or complications during delivery), nursing, have asthma, or have stomach problems (such as heartburn, upset stomach or stomach pain) that persist or recur, or if you have ulcers or bleeding problems, unless directed by a physician. If ringing in the ears or temporary loss of hearing occurs, consult a physician before taking again.

DRUG INTERACTION PRECAUTION: Do not take this product if you are taking MAO inhibitors or a prescription drug for anticoagulation (thinning of the blood), diabetes, gout or arthritis, or any other prescription drug unless directed by a physician. This product is not intended for pain relief, fever, toothache, or any other analgesic effect.

Keep out of the reach of children. Children and teenagers should not use this product, or any other product containing aspirin, for chicken pox or flu symptoms before a physician is consulted about Reye Syndrome, a rare but serious illness reported to be associated with aspirin. In case of overdose, get medical help or contact a Poison Control Center right away.

ALCOHOL WARNING: If you consume 3 or more alcoholic drinks every day, ask your physician whether you should take aspirin. Aspirin may cause stomach bleeding.

AC WATERHOUSE Distributed by A.G. Waterhouse™