

SEP 09 2004

Dragon Herbs

315 Wilshire Blvd., Santa Monica, CA 90401
Tel: (310) 917-2288 Fax: (310) 917-1134

September 1, 2004

Dr. Robert J. Moore
Branch Chief, Compliance & Enforcement Branch
Office of Nutrition Products, Labeling & Dietary Supplements
Food & Drug Administration (HFS-800)
5100 Paint Brush Parkway
College Park, Maryland 20740

SEP 8 0 2004

Ref: Notifications for 7 Dragon Herbs products

Dear Dr. Moore,

Attached please find notifications being filed on behalf of Dragon Herbs, the distributor of the products which bear the statements identified in these notifications. The notifications are being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. (101.93).

Notifications attached are being filed for the following products:

1. Duanwood Reishi – 100 capsules
2. Cordyceps – 100 capsules
3. Pearl– 100 capsules
4. Eleuthero – 2 fl. oz. extract
5. Natural Plant Extract Powder 50204-001– 1 kg (for further processing and packaging only)
6. Natural Plant Extract Powder 50204-002– 1 kg (for further processing and packaging only)
7. Natural Plant Extract Powder 50204-003– 1 kg (for further processing and packaging only)

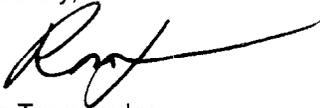
Labels of these products are hereby attached.

Please be advised that we have substantiation on file that these claims are truthful and not misleading.

Should your office have any questions, please do not hesitate to contact us immediately.

We are more than willing to provide additional information for your review and to revise any claims and statements that your office finds necessary for revisions.

Sincerely,



Ron Teeguarden
President of Dragon Herbs

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Manufactured by:
Dragon Herbs
Santa Monica, CA 90401



This product is not intended to diagnose, cure, or prevent any disease.

Dragon Herbs



Duanwood Reishi
#514 Dietary Supplement

100 Capsules 500mg each

Supplement Facts

Serving Size 1 Capsule

	Amount per Serving	% Daily Value
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100% Duanwood Reishi (Gandoderma Lucidum, fruiting body)	500mg	†
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† Daily value not established

Other Ingredients:

Gelatin, water, and glycerin

Directions:

Take 2 capsules, 3 times a day or as directed

Manufactured by:
Dragon Herbs
Santa Monica, CA 90401



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Dragon Herbs



Cordyceps
#506 Dietary Supplement

100 Capsules 500mg each

Supplement Facts

Serving Size 1 Capsule

	Amount per Serving	% Daily Value
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Cordyceps Mycelium	500mg	†
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† Daily value not established

Other Ingredients:

Gelatin, water, and glycerin

Directions:

Take 2 capsules, 3 times a day or as directed

Manufactured by:
Dragon Herbs
Santa Monica, CA 90401



This product is not intended to diagnose, cure, or prevent any disease.

Dragon Herbs



Pearl
#539 Dietary Supplement

100 Capsules 500mg each

Supplement Facts

Serving Size 1 Capsule

	Amount per Serving	% Daily Value
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Pearl Powder (100% pure fresh water pearls)	500mg	†
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† Daily value not established

Other Ingredients:

Gelatin, water, and glycerin

Directions:

Take 2 capsules, 3 times a day or as directed

Manufactured by:
Dragon Herbs
Santa Monica, CA 90401



This product is not intended to diagnose, cure, or prevent any disease.

Dragon Herbs



Eleuthero
#020 Dietary Supplement

Supplement Facts

Serving Size 1 squirt

Servings per container 80 squirts

	Amount per Serving	% Daily Value
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Eleuthero (root)	55.025	†
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† Daily value not established

Directions:

Take 3-12 droppers per day, or as directed

Shake well before use

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Ron Teeguarden, President

SEP 20 2004

**NOTIFICATION PURSUANT
TO SECTION 6 OF DSHEA
AND 21 C.F.R. (101.93)**

This notification is being filed on behalf of Dragon Herbs, the distributor of the products which bear the statements identified in this notification. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. (101.93). The dietary supplement on whose labeling the statements appear is "**CORDYCEPS.**"

The principle display panel bears no structure/function statements. The panel does include the following DSHEA statement: "This product is not intended to diagnose, treat, cure or prevent any disease."

Labeling for this product other than the principle display panel bears structure/function statements provided for in Section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act.

The structure/function statements for which notification is now being given, which are based on credible third-party substantiation on file in our office, are:

- Cordyceps is restorative after excessive exertion.
- Cordyceps may improve physical endurance.
- Cordyceps helps restore cellular energy levels after adapting to stress.
- Cordyceps helps boost functions associated with the adrenal cortex that aid in the adaptation to stress.
- Cordyceps increases respiratory efficiency.
- Cordyceps increases respiratory capacity.
- Cordyceps is an immune modulating agent.
- Cordyceps is an immune-potentiating agent.

TRADITIONAL USES (referenced from standard Chinese herbal texts)

- Cordyceps tonifies Qi.
- Cordyceps replenishes Yin and Yang Jing.
- Cordyceps is used to strengthen the body and mind.
- Cordyceps is believed in the Orient to have rejuvenation functions.
- Based on the belief that Cordyceps replenishes Yin and Yang Jing, Cordyceps is believed in the Orient to have anti-aging functions.
- Cordyceps is also a Lung* tonic.
- Cordyceps is used for the purposes of strengthening the primal Kidney* functions, which include sexual functions, brain power, structural integrity and healing ability, according to traditional Chinese health theory.
- Cordyceps can have a benefit in the vascular system.
- Cordyceps improves the function of the micro-circulation and improves efficiency at the capillary level.
- Cordyceps has been shown to help regulate blood pressure and to strengthen heart muscle.

The following statement is adjacent to the "Traditional Uses" statements: "When the organ name refers to the traditional Chinese concept of that *organ-function*, the *organ-function* name is capitalized. When an name refers to the conventional western definition of an organ, it is not capitalized.

Adjacent to all these statements is a ruled DSHEA disclaimer: "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."

We have substantiation on file that these claims are truthful and not misleading.

Dragon Herbs

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Ron Teeguarden, President

SEP 20 2

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

This notification is being filed on behalf of Dragon Herbs, the distributor of the products which bear the statements identified in this notification. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. (101.93). The dietary supplement on whose labeling the statements appear is "**ELEUTHERO**"

The principle display panel bears no structure/function statements. The panel does include the following DSHEA statement: "This product is not intended to diagnose, treat, cure or prevent any disease."

Labeling for this product other than the principle display panel bears structure/function statements provided for in Section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act.

The structure/function statements for which notification is now being given, which are based on credible third-party substantiation on file in our office, are:

- Eleuthero (Radix Eleutherococcus senticosus) is an adaptogenic herb that improves the ability to handle stress.
- Eleuthero has been shown to reduce the activation of the adrenal cortex in response to stress.
- Eleuthero helps to increase physical and mental endurance.
- Eleuthero helps to improve memory.
- Eleuthero benefits mental and physical endurance.
- Eleuthero has anti-fatigue activity.
- Eleuthero aids in the recovery from hard exercise.
- Eleuthero aids in the recovery from mental exertion.
- Eleuthero has been shown to improve mental alertness and work output.
- Eleuthero improves the ability of the body to absorb and efficiently use oxygen.
- Eleuthero helps to build blood.
- Eleuthero is an immune modulator.
- Eleuthero is a mild stimulant.
- Eleuthero has a detoxifying action, protecting animals against various poisons.
- Eleuthero has been shown to promote antibody formation.

TRADITIONAL USES (referenced from standard Chinese herbal texts)

- Eleuthero reinforces Qi

Adjacent to all these statements is a ruled DSHEA statement: "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."

We have substantiation on file that these claims are truthful and not misleading.

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