



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR - 3 2007

Ms. Joan R. Smith
President and CEO
Kura Natural, Inc.
PO Box 996
Danville, California 94526

Dear Ms. Smith:

This is in response to your letter of March 19, 2007 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 Kura Natural, Inc. is making the following claim, among others, for the product **Kolchisponin**:

“[M]ay help lower blood pressure....”

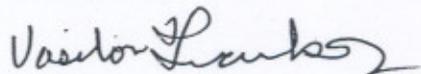
21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate diseases (i.e., hypertension or high blood pressure). This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

97S 0163 LET 934

Page 2 - Ms. Joan R. Smith

Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.
Director
Division of Dietary Supplement Programs
Office of Nutrition, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, San Francisco District Office, Office of Compliance, HFR-PA140

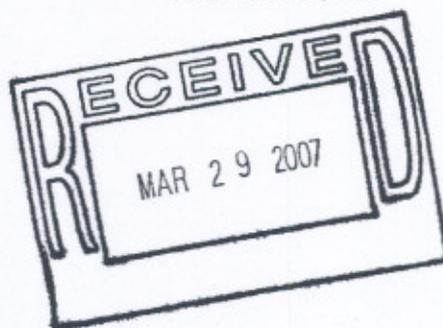
Kura Natural

KURA NATURAL, INC
PO Box 996, Danville, CA 94526
925-314-9032 · FAX: 925-937-6291

JOAN R SMITH, CEO

March 19, 2007

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
FOOD AND DRUG ADMINISTRATION
200 C Street, S.W.
Washington, DC 20204



Ref.: Kolchisponin – Dietary Supplement

Dear Sir or Madam:

Pursuant to 21 CFR 101.93, please be advised that Kura Natural, Inc. has begun commercializing Kolchisponin – Dietary Supplement.

Kolchisponin – is labeled and promoted with statements provided for in section 403(r)(6) for the Federal Food, Drug, and Cosmetic Act.

1. **LABEL**

(Note: the asterisks appearing in the copy below are related to the ruled DSHEA disclaimer box which is asterisked and appears on the product literature.)

Kolchisponin is an extract of the flowering species *Tribulus terrestris* (puncture vine). Kolchisponin contains 30% furostanolic glycosides. and 6% flavonoids (astragalins and rutin).

Tribulus terrestris has been popular for its role in supporting reproductive function, cardiovascular health, and for increasing stamina. Studies have also shown that *Tribulus terrestris* may help lower blood pressure and may have antioxidant properties.**

2. **KURA NATURAL INC. WEB SITE**

(Note: the asterisks appearing in the copy below are related to the ruled DSHEA disclaimer box which is asterisked and appears on the product literature.)

Kolchisponin is an extract of the flowering species *Tribulus terrestris* (puncture vine). Kolchisponin contains 30% furostanolic glycosides. and 6% flavonoids (astragalins and rutin).

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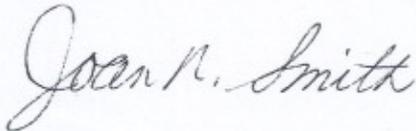
2007-2075

Product labeling and literature prominently bears the required box 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."

Kura Natural, Inc. certifies that the information contained in this notice is complete and accurate, and the company has substantiation that the foregoing statements are truthful and not misleading.

Please do not hesitate to advise should you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Joan R. Smith".

Joan R. Smith
President and CEO

Attachments: Kolchisponin – Dietary Supplement
Copy of Web Site (including references to literature)
Label

Kolchisponin

Cardiovascular and Reproductive System Support

Kolchisponin is an extract of the flowering species *Tribulus terrestris* (puncture vine). Kolchisponin contains 30% furostanolic glycosides and 6% flavonoids (astragalin and rutin).

Tribulus terrestris has been popular for its role in supporting reproductive function, cardiovascular health, and for increasing stamina. Studies have also shown that *Tribulus terrestris* has antioxidant properties and that it may help lower blood pressure.**

Supplement Facts

Serving Size: 1 Tablet

Servings Per Container: 200

Amount Per Capsule	%Daily Value †
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Extract of <i>Tribulus terrestris</i> 100 mg (standardized to 30% saponins)	**
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† Percent Daily Values are based on a 2,000 calorie diet
** Daily Value not established

Active Ingredients

Each 100 mg. tablet contains extract of *Tribulus terrestris* (standardized to 30% saponins).

Other Ingredients

Lactose, stearic acid, starch. CONTAINS NO YEAST, ARTIFICIAL FLAVORS, ARTIFICIAL COLORS OR ARTIFICIAL SWEETENERS.

Directions

Take one to two tablets, before meals, three times a day for 14 days. Repeat course after one week rest.

Warnings

Pregnant or lactating women, diabetics, hypoglycemics, and people with known medical conditions and/or taking drugs should consult with a licensed physician and/or pharmacist prior to taking dietary supplements.

Side Effects

Through-passing nausea, sweaty, indulgence, skin itch.

Storage

Store in a cool, dry place away from children.

Shelf Life

2 years.

Research Publications and References

406 cases of angina pectoris in coronary heart disease treated with saponin of *Tribulus terrestris*
Zhong Xi Yi Jie He Za Zhi. 1990 Feb;10(2):85-7, 68. [Article in Chinese] Wang B, Ma L, Liu T.

Tribulusamide A and B, new hepatoprotective lignanamides from the fruits of *Tribulus terrestris*:
indications of cytoprotective activity in murine hepatocyte culture.
Planta Med. 1998 Oct;64(7):628-31. Li JX, Shi Q, Xiong QB, Prasain JK, Tezuka Y, Hareyama T, Wang
ZT, Tanaka K, Namba T, Kadota S. PMID: 9810268

Effect of *Tribulus terrestris* L. saponin mixture on some smooth muscle preparations: a preliminary
study.
Boll Chim Farm. 1998 Dec;137(11):473-5. Arcasoy HB, Erenmemisoglu A, Tekol Y, Kurucu S, Kartal M.
PMID: 10077881

Proerectile pharmacological effects of *Tribulus terrestris* extract on the rabbit corpus cavernosum.
Ann Acad Med Singapore. 2000 Jan;29(1):22-6. Adaikan PG, Gauthaman K, Prasad RN, Ng SC. PMID:
10748960

The effects of *Tribulus terrestris* on body composition and exercise performance in resistance-trained
males
Int J Sport Nutr Exerc Metab. 2000 Jun;10(2):208-15.. Antonio J, Uelmen J, Rodriguez R, Earnest C.
PMID: 10861339

Selected herbals and human exercise performance.
Am J Clin Nutr. 2000 Aug;72(2 Suppl):624S-36S. Bucci LR.

New steroidal glycosides from the fruits of *Tribulus terrestris*.
J Nat Prod. 2000 Dec;63(12):1699-701. Bedir E, Khan IA. PMID: 11141122

Effect of the decoction of *tribulus terrestris* on mice gluconeogenesis
Zhong Yao Cai. 2001 Aug;24(8):586-8. [Article in Chinese] Li M, Qu W, Chu S, Wang H, Tian C, Tu M.
[Source IBIDS]

Endocrine and lipid responses to chronic androstenediol-herbal supplementation in 30 to 58 year old
men.
J Am Coll Nutr. 2001 Oct;20(5):520-8. Brown GA, Vukovich MD, Martini ER, Kohut ML, Franke WD,
Jackson DA, King DS. PMID: 11601567

Hypoglycemic effect of saponin from *Tribulus terrestris*
Zhong Yao Cai. 2002 Jun;25(6):420-2. [Article in Chinese] Li M, Qu W, Wang Y, Wan H, Tian C.

Evaluation of natural products on inhibition of inducible cyclooxygenase (COX-2) and nitric oxide
synthase (iNOS) in cultured mouse macrophage cells.
J Ethnopharmacol. 2002 Nov;83(1-2):153-9. Hong CH, Hur SK, Oh OJ, Kim SS, Nam KA, Lee SK.

Aphrodisiac properties of *Tribulus Terrestris* extract (Protodioscin) in normal and castrated rats.
Life Sci. 2002 Aug 9;71(12):1385-96. PMID: 12127159

Determination of steroidal saponins in *Tribulus terrestris* by reversed-phase high-performance liquid
chromatography and evaporative light scattering detection.
J Pharm Sci. 2001 Nov;90(11):1752-8. Ganzera M, Bedir E, Khan IA. PMID: 12016919

Experimental *Tribulus terrestris* poisoning in sheep: clinical, laboratory and pathological findings.
Vet Res Commun. 2003 Jan;27(1):53-62. Aslani MR, Movassaghi AR, Mohri M, Pedram M, Abavisani A.
PMID: 12625403

The inhibitory effect of saponins from Tribulus terrestris on Bcap-37 breast cancer cell line in vitro
Zhong Yao Cai. 2003 Feb;26(2):104-6. PMID: 12795220

Tribulus terrestris: preliminary study of its diuretic and contractile effects and comparison with Zea mays.
J Ethnopharmacol. 2003 Apr;85(2-3):257-60. Al-Ali M, Wahbi S, Twaij H, Al-Badr A. PMID: 12639749

Effect of saponin from Tribulus terrestris on hyperlipidemia
Zhong Yao Cai. 2003 May;26(5):341-4. hu S, Qu W, Pang X, Sun B, Huang X. PMID: 14535016

Furostanol saponins from Tribulus terrestris.
Fitoterapia. 2003 Sep;74(6):583-91. De Combarieu E, Fuzzati N, Lovati M, Mercalli E. PMID: 12946722

Study of antihypertensive mechanism of Tribulus terrestris in 2K1C hypertensive rats: role of tissue ACE activity.
Life Sci. 2003 Oct 24;73(23):2963-71.

Terrestrinins A and B, two new steroid saponins from Tribulus terrestris.
J Asian Nat Prod Res. 2003 Dec;5(4):285-90.

A novel furostanol saponin from Tribulus terrestris of Bulgarian origin. PMID: 15030914
Fitoterapia. 2004 Mar;75(2):117-22.

Investigation on inhibitory and apoptosis-inducing effects of saponins from Tribulus terrestris on hepatoma cell line BEL-7402
Zhongguo Zhong Yao Za Zhi. 2004 Jul;29(7):681-4. PMID: 15503780

Effect of Tribulus terrestris on nicotinamide adenine dinucleotide phosphate-diaphorase activity and androgen receptors in rat brain.
J Ethnopharmacol. 2005 Jan 4;96(1-2):127-32.

Antifungal activities and action mechanisms of compounds from Tribulus terrestris L.
J Ethnopharmacol. 2005 Sep 14; PMID: 16169173

Experimental study of saponins from Tribulus terrestris on renal carcinoma cell line
Zhongguo Zhong Yao Za Zhi. 2005 Aug;30(16):1271-4. PMID: 16245908



produced by:
Iovel Kutateladze Institute of Pharmacochemistry
P. Sarajishvili Street 36
0159, Tbilisi, Georgia

**** 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.**

V. Gorgasali St. #37, Tbilisi 0114, Republic of Georgia · (995-32) 75-2627 · kuranatural@kura-natural.com

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Kolchisponin is an extract of the flowering species Tribulus terrestris (puncture vine). Kolchisponin contains 30% furostanolic glycosides, and 6% flavonoids (astragaloside and rutin).

Tribulus terrestris has been popular for its role in supporting reproductive function, cardiovascular health, and for increasing stamina. Studies have also shown that Tribulus terrestris may help lower blood pressure and may have antioxidant properties.**



produced by:
Iovel Kutateladze Institute of Pharmacochemistry
P. Sarajishvili Street 36
0159, Tbilisi, Georgia

Store in a cool, dry place away from children.

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Kura Natural
CAUCASIAN HERBS AND SUPPLEMENTS
EXTRACT OF TRIBULUS TERRESTRIS
KOLCHISPONIN
DIETARY SUPPLEMENT
CARDIOVASCULAR AND REPRODUCTIVE SYSTEM SUPPORT

100 MG
200 TABLETS

Supplement Facts

Serving Size: 1 Tablet
Servings Per Container: 200

Amount Per Tablet	%Daily Value †
Extract of Tribulus terrestris 100 mg (standardized to 30% saponins)	**

† Percent Daily Values are based on a diet of 2,000 calories per day.
** Daily Value not established.

OTHER INGREDIENTS

Lactose, stearic acid, starch. CONTAINS NO YEAST, ARTIFICIAL FLAVORS, ARTIFICIAL COLORS OR ARTIFICIAL SWEETENERS.

DIRECTIONS

Take one to two tablets, before meals, three times a day for 14 days. Repeat course after one week rest.

WARNING

Pregnant or lactating women, diabetics, hypoglycemics, and people with known medical conditions and/or taking drugs should consult with a licensed physician and/or pharmacist prior to taking dietary supplements.

Lot No:
Exp Date:

Distributed by
Kura Natural, Inc.
Danville, CA 94526
USA

