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Mr. Christopher A. Smith
Camelyn USA, Inc.
PO Box 996
Danville, California 94026

Dear Mr. Smith:

This is in response to your letter of August 9, 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 Healthcare Camelyn USA, Inc. is making the following claims, among others, for the product Dried Extract of Kolkheti Honey:

"[H]oney and bee products have...anti-bacterial, anti-viral, anti-fungal and anti-inflammatory properties."

"[P]romote healing."

"[P]romote healing diabetic ulcers and chronic wounds."

"[T]reatment of infection, inflammation, non-healing wounds and tumors..."

"[H]as...anti-bacterial, healing...properties."

"[A]ntibacterial properties of honey increase as the concentration increases."

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 this product suggests that it is intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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 your client intends to make claims of this nature, they 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.

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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



CAMELYN USA

CHRISTOPHER SMITH, VP AND DIRECTOR
PO BOX 996, DANVILLE, CA 94026 USA

August 9, 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.: Dried Extract of Kolkheti Honey – Dietary Supplement

Dear Sir or Madam:

Pursuant to 21 CFR 101.93, please be advised that Kura Natural, Inc. has begun commercializing Dried Extract of Kolkheti Honey – Dietary Supplement.

Dried Extract of Kolkheti Honey – Dietary Supplement 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.)

Kolkheti Honey Dried Extract is a unique extract of honey from the region of Georgia that the ancient people called Kolchis. All of the water, sugar and protein have been removed, leaving only the active ingredients of the honey.

Scientific studies suggest that honey and bee products have antioxidant, anti-bacterial, anti-viral, anti-fungal and anti-inflammatory properties. Further, studies have suggested that honey can promote healing and provide immune system support. Honey has been shown to promote healing of diabetic ulcers and chronic wounds **.

2. CAMELYN USA. WEB SITE AND MARKETING BROCHURES

(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.)

The medicinal efficacy of the honey from this part of the world is legendary and was documented by early writers that include the ancient Greek historian Xenofont. The 12th Century Georgian medical publication "Tsigni Saakimoi" contains more than 160 prescriptions of treatment of infection, inflammation, non-healing wounds and tumors with Kolkheti honey. More recently the honey of Kolchis is documented by Eli Smith (1801-1857) the American missionary and orientalist; Edmond Spencer in his book "Voyage Along Cherkezia, Abkhazia and Megrelia"; and the 19th Century English scientist Pevi all tout the effectiveness of honeys of this region.

Our extract is produced via a patented extraction technique that removes all sugars, proteins and water leaving only the active ingredients: a complex mixture of flavonoids, amino acids, antioxidants and minerals.

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Honey, which consists of over 96% sugar, water and protein, is added to many foods and cosmetics and for very good reasons: in varying degrees -- depending on the region in which it is produced -- honey has anti-oxidant, anti-bacterial, healing and preservative properties. Many scientific studies have shown that honeys of the Caucasus have such properties that match or exceed the capabilities of all know medicinal honeys.

Using Kolkheti Honey as an additive, a product manufacturer can achieve the effect of adding large amounts of honey without overwhelming the product with sugar or other undesirable elements. Kolkheti Honey Extract is water-soluble and blends equally well with oil-based products.

It has been demonstrated via scientific experiments that the antibacterial properties of honey increase as the concentration increases. There are of course physical limits to the amount of plain honey that an individual can ingest in order to achieve a therapeutic effect, making a highly concentrated product highly effective.

There are no chemical alterations to this 100% natural honey product. There are no other ingredients added, except as indicated for reduction of moisture. Kolkheti Honey is a pure, wild and ecologically clean honey. **

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.

Camelyn USA, 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,



Christopher A. Smith
VP and Director, Camelyn USA, Inc.
PO Box 996
Danville, CA 94026 USA
Phone: 925-314-9032 / mobile: 925-984-9446

Attachments:

Sample Label
Document: Kolkheti Honey Extract"
List of Supporting Literature