



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

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OCT 15 2003

Ms. Gladys Valencia  
Director  
HerbsForever, Inc.  
501 S. Harvard Boulevard, #2  
Los Angeles, California 90020

Dear Ms. Valencia:

This is in response to your letter to the Food and Drug Administration (FDA), dated September 16, 2003, 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 HerbsForever, Inc. is marketing the products **Hair Plus, Maha Masha oil, Sirodhara oil, Flexn oil, Silfina oil, Brahmi Hair Oil, Almond Oil, Kapha oil** for various external or topical uses.

The products are described as "For external use only" (Hair Plus, Maha Masha oil, Sirodhara oil, Flexn oil, Silfina oil, Kapha oil), for "use as Herbal scalp skin tonic" (Brahmi Hair Oil), or as a "superb natural moisturizer, very beneficial to dry skin" and "useful for Hair, Skin and Body massage if used externally" (almond oil).

These products do not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, can not be marketed as dietary supplements. We explain the basis for our opinion below.

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 diet, and are labeled as a dietary supplement.

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An article that is applied externally to the skin is not "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.")...

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 intended to be used topically are not subject to regulation as dietary supplements because they are not "intended for ingestion" and are drugs under 21 U.S.C. 321(g)(1)(C) because they are articles (other than food) intended to affect the structure or function of the body.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

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**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, Los Angeles District Office, Compliance Branch, HFR-PA240**

# Herbsforever, Inc.

501 S. Harvard Blvd., #2  
Los Angeles, California 90020

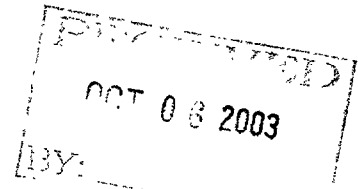
Tel: (213) 427-3500  
Fax: (213) 383-3076

Email: [Vijayshantikumar@yahoo.com](mailto:Vijayshantikumar@yahoo.com)

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Sep16, 2003

Dr. Elizabeth Yetley  
Office of Special Nutrition (HFS-450)  
Center of Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street S.W.  
Washington, DC 20204



Re: Notification of Product Claims

Dear Dr. Yetley:

This letter serves as notification of the nutrition support labeling statements being made by our company in connection with our line of dietary nutritional supplements. A list of the products and their respective nutritional support statements and ingredients are listed in the attached Exhibit "A".

Herbsforever certifies that the information contained in this notice is complete and accurate, and the company maintains documentation to substantiate that its product claims are truthful and not misleading.

If you have any questions, please feel free to contact me and I will do my best to answer your questions.

Gladys Valencia  
Director  
Herbsforever, Inc.

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## **EXHIBIT "A"**

HERBSFOREVER, INC.

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### **Garlic**

Circulatory Effects & Anti-oxidant.

Supports a healthy circulation, digestive & immune system. Blood and lymph cleanser  
Nerve & Bone Tissue rasyana (Rejuvenate) Vayu/Kapha rasyana.\*\*

A Dietary Supplement Research studies indicate that consumption of Garlic helps to maintain healthy cholesterol and blood pressure level which is already within the normal limits As a rejuvenator inclusion of Garlic in diet offer another step to good health.\*\*

Note: Garlic is hot in nature, as per Ayurvedic theory (Indian Herbal System). Woman during menopause period should avoid or take less Garlic.

Ingredients: Garlic (Allium Sativum)

### **Sesame oil**

**Ingredients:** Cold pressed fixed oil of Sesamum indicum seeds The finest Sesamum seeds are mechanically cold pressed (at a temperature below 450C) and then filtered.

### **Sun flower oil**

**Ingredients:** Cold pressed fixed oil of Helianthus annus seeds

The finest Helianthus annus seeds are mechanically cold pressed (at a temperature below 45 0 C) and then filtered.

### **Castor oil**

**Ingredients:** Cold pressed fixed oil of Ricinus communis.

The finest Ricinus communis seeds are mechanically cold pressed (at a temperature below 45 0 C) and then filtered.

### **Mustard oil**

**Ingredients:** Cold pressed fixed oil of Brassica juncea seeds.

The finest Brassica juncea seeds are mechanically cold pressed (at a temperature below 45 0 C) and then filtered.

### **Hair plus**

A Natural Herbal Hair Rejuvenator Natural sweet fragrance.

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For external use only.

Use: As Herbal scalp skin tonic. All the herbs used in Hair plus has safe history of usage in Ayurveda (Science of life) for rejuvenation and nourishment of healthier hair and scalp.\*\*

Naturally supports healthy hair for young look.

Note: This herbal oil is more beneficial to use with our other product Hair Gain which is herbal supplement to enhance fast effective results.

**Ingredients:**

Sesame Oil (Sesamum indicum) Processed with decoctions of Jasmine , Emblica Officinalis ,Centella Asiatica , Bacopa monnieri , Terminalia belerica Terminalia chebula, Lawsonia alba, Licorice , Musk Root , Cyperus rotundus, Cuscuta reflexa , Eclipta alba , Citrullus colcyntis (Indrayan Bitter apple) , Indigofera tintocria , Abrus precatorius (Indian licorice Gunja) ,Berberis aristata (indian barberry) ,Pongamia Glabra, Azadirachta Indica , Inula racemosa ,Cardamom, Curcuma zedoaria, Rubia cordifolia , Sida cordifolia Seeds , Psoralea corylifolia, Indian Sarsaparilla (Hemidesmus indicus),Lemon (Citrus medica) oil.

**Black salt**

Helps to Promote Healthy Digestive System & Gastrointestinal Tract; Supports Digestive fire & Food Absorption. Helps to maintain Healthy liver functions Beneficial to eyes\*\*

A Dietary supplement: Sanskrit name: Krishna Lavana commonly known as Kala Nimak or Black Mineral Natural salt.

The mineral salt exist in nature in natural way (also known as Rock salt) is mixed with herbs Amla (Emblica Officinalis ), Terminalia chebula and heated red hot for purification as per Ayurvedic way (Indian Herbal System). After purification, It is made in powder form.

As per Ayurvedic literature (Indian Herbal System) Black salt which is Natural Mineral Organic salt is superior and healthier than ordinary chemical salt which is prepared by drying and purification of sea water.

**Maha masha oil**

Natural Herbal Joint and muscle oil.

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For external use only

Maha Masha oil: Highly recommended for old Vatta and Kapha dosha conditions as per Ayurvedic theory of Tridosha: Vatta (air), Pitta (fire), Kapha (water).

Note: This product is highly recommended to use with our other product Joint Health, which is herbal supplement to enhance fast effective results.

This Maha Masha oil is an original receipe according to the original text of Ayurveda thousand

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years old.

**Ingredients:**

Sesame oil Processed with decoction of:

Withania somnifera  
Kachur(Zedoaria)  
Cedrus deodara  
Sida cordifolia  
Pluchea lanceolata  
Paederia fotida  
Sarcostigma kleinii  
Populus ciliata  
Clerodendron serratum  
Ipomea digitata  
Cumin  
Verbascum thapsus  
Boerhaavia diffusa  
Lemon  
Asperagus racemosus  
Black cumin  
Ferula assafoetida  
Foeniculum vulgare  
Tribulus terresteris  
Piper nigrum  
Plumrargo zeylanica  
Rock salt  
Meda  
Polygonatum cirrihifolium  
lilium polyphyleum  
Kshirkakoli  
Microstylis mucifera  
Microstylis wallichi  
Hebenaria intermedia  
Licorice  
Santaloid desminus

Dendrovium macrael  
Cow's milk  
Black gram

### **Sirodhara oil**

Natural Herbal Nervine & Body massage oil

For external use only

KASHIR BALA is the guaranteed original Ayurvedic oil recipe as per Ayurvedic text books. It has been used in Ayurveda (thousands of years old) for body massage (Abhyanga & Nasya) .\*\*

Slowly and wonderfully, this natural herbal oil will give you a Relaxing feeling.

**Ingredients:** Sesame oil (Sesamum indicum) Khareti (Sida Cordifolia) (Processed in sesame oil) Camphor (Camphora officinarum) oil ,Milk fat

### **Hair gain**

NATURAL HERBAL HAIR CARE

Promotes healthy lustrous hair. As a unique body tonic, supports vision and healthy brain functioning.\*\*

Dietary supplement: All the herbs used in Hair gain have safe history of usage in Ayurveda (Indian Herbal System) for rejuvenation and nourishment of healthier hair and scalp.\*\*

This Herbal Hair Rejuvenator Formula Supports nourishment of hair roots and scalp. Supports blood circulation to hair follicle. Helps to maintain growth of thicker, healthier & longer hair. Supports healthy hair for young look.\*\*

**Note:** This product is beneficial to use with our other product Hair plus, which is herbal hair oil to enhance fast effective results.

**Ingredients:**

Emblica officinalis, Terminalia belerica, Terminalia chebula, Iron oxide (Loh Bhasma), Licorice , Eclipta alba.

### **Ghee**

Helps to increase Marrow, Semen & Ojas (Immune). Supports healthy Vision, Voice, Intelligence and Brain. It transports nutrients & energy to all tissue layers\*\*.

Ghee: lubricates and moistens the membranes and tissues. Helps in the proper flowing of wastes and toxins from the body. Person with strong digestion can use more ghee or less in case of weak digestion.



A Dietary Supplement: Shatavari is cool herb by nature as per Ayurvedic theory of 3 doshas (literally means vatta-air, Pitta-fire, Kapha- water). Useful in both male and female for healthy reproductive organs and urinary tract. A herb of choice useful for menopausal woman and lactating females. Shatavari has been safely used in Ayurveda (Indian Herbal System) for thousand of years for fertility and vitality. This Ayurvedic Rejuvenative herb is used in many tonics and numerous Ayurvedic herbal formulas.

**Ingredients:**

Shatavari (*Asparagun racemosus*)

**Flexn oil**

Natural Herbal Joint & Muscle Oil

For external use only.

Slowly and wonderfully, this natural herbal thick cream will give you a warm, stimulating feeling\*

Note: Use of this product is highly recommended with our other product Joint Health which is herbal supplement to enhance fast effective results.

**Ingredients:**

Turmeric (*Rhizome*)

Ginger (*Rhizome*)

Turpentine oil (*Pinus Longifolia*)

Sesamum oil

Liquid Paraffin

Camphor

Eucalyptus oil

Capsicum oil

Gandapuro oil (*Gaultheria Fragrantissima*)

Peppermint (*Mentha Piperita*)

**Silfina oil**

Natural Herbal Skin Care. Promotes Skin Health.

For external use only: All the herbs used in Silfina oil has safe history of usage in Ayurveda (Indian Herbal System) as pitta balancer for healthier smooth skin.\*

Silfina oil is highly recommended for the people who have high Pitta (fire) as per Ayurvedic theory of Tri dosha vatta (air) Pitta (fire) Kapha (water).

Note: This herbal Silfina oil is more beneficial to use with our other product Blood cleaner which is herbal supplement to enhance fast effective results.

**Ingredients:**

Curcuma longa

Mustard seed oil (Sarson) (*Brassica juncea*)

pongamia glabra.  
Olea europaea  
Azadirachta indica  
Brassica nigra  
Cassia tora  
Psoralea corylifolia  
Lawsonia Alba

### **Brahmi Hair Oil**

A Natural Herbal Hair Rejuvenator. Natural sweet fragrance.

Use As Herbal scalp skin tonic. All the herbs used in this oil has safe history of usage in Ayurveda (Science of life) for rejuvenation and nourishment of healthier hair

Note: This herbal oil is more beneficial to use with our product Hair Gain which is herbal supplement to enhance fast effective results.

In Ayurveda for promoting intelligence, improving memory and revitalization of the five sense organs. A specially prepared paste of the entire plant is made with Sesame seeds in formulating this famous oil.

Brahmi often called the food of the brain. Use in Ayurveda to calm mind and Pacify Pitta.

#### **Ingredients:**

Sesame seed (Sesamum indicum). Oil processed with Brahmi(Bacopa monnieri) (Equal quantity of Brahmi( Bacopa monnieri) is processed in Sesame Oil)

### **Neem Oil**

Cold pressed fixed oil of Azadirachta indica seeds in a base of refined Sesame oil

The finest Neem (Azadirachta indica) seeds are mechanically cold pressed (at a temperature below 45 0 C) with refined Sesame oil and then filtered.

### **Basil oil**

Essential oil by steam distillation from the leaves and flowering tops.

The sanskrit name of Holy basil is Tulsi. This sacred plant is cherished in every Hindu house for healthy body and soul.

### **Almond oil**

Cold pressed fixed oil of almonds seeds is rich in vitamin A & E. A superb natural moisturizer,very beneficial to dry skin. Almond Oil is highly recommended for the peoples who have vatta conditions as per Ayurvedic theory of Tridosha vatta (air) Pitta (fire) Kapha(water).

The finest sweet almonds (*Prunus amygdalus*) seeds are mechanically cold pressed (at a temperature below 450 C) and then filtered.

Almond oil is one of the traditional oil in Ayurveda, useful for Vatta. In India it is taken traditionally, with hot milk good for brain as rich natural source of vitamin A. Take away dryness of skin and inside the body as a natural lubricant. Almond oil is useful for Hair, Skin and Body massage if used externally.

### **Kapha oil**

Supports healthy Relaxing feeling in weather and environmental changes conditions.

For external use only

As per Ayurvedic theory of Tri Dosha (Vatta- air, Pitta-fire, Kapha-water). Kapha

element increases in the body during the beginning and end of the winter seasons.

People with lack of interest in food regularity, sweet and watery taste of mouth, heaviness in stomach and chest are assumed to have high Kapha element in the body.

All herbs contained in Kapha oil have a safe & long history of usage in Ayurveda (Indian Herbal System) for many centuries.

Slowly and wonderfully, this natural herbal oil will give you a relax and warm, stimulating feeling.\*

#### **Ingredients:**

Peppermint (*Mentha piperita*)  
Camphor oil (*Camphora officinarum* oil)  
Ajowan oil (*Ptychotis Ajowan* oil)  
Liquid paraffin  
Nutmeg oil (*Myristica fragrans* oil)  
Nilgiri oil (*Eucalyptus Globulus*)  
Turpentine oil (*Pinus longifolia*)  
Sesame oil.

### **Ashwagandha**

Ayurvedic Rejuvenative Botanica.

Helps to improve Physical and Mental ability. Supports Energy, Stamina and Vitality.

Natural tonic provides overall health\*\*

A Dietary Supplement : Sanskrit name Ashwagandha literally means Horse vitality. This is one of the most famous herb in Ayurveda (Science of life). Some studies have shown that this herb is more superior and effective than korean Ginseng, has been safely used in Ayurvedic (Indian Herbal System) for thousand of years. This Ayurvedic Rejuvenative herb is used in many tonics and formulations\*\* With Recommended daily dose, you may begin to notice benefits in as little as few days.