



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

0765 5 NOV -7 P1:57

SEP 22 2005

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 July 11, 2005, 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 **Almond Oil, Apricot Oil, Babchi Seeds Oil, Castor Oil, Coconut Oil, Mustart Oil, Neem Oil, Sesame [sic] Oil, Sunflower Oil, Blossom Hair Oil, Brahmi Amla, Brahmi Oil, Flexn Oil, Gloris Oil, Kapha Oil, Maha Masha Oil, Maha Narayana Oil, Mahavishgarba Oil, Nasya Oil, Silfina Oil, Sirodhara Oil, Wholy Oil Bath, and Wondruff Oil.** for various external or topical uses.

The products are described as "For external use only." 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.

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

97S 0163 LET 843

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

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

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July 11, 2005

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

AUG 11

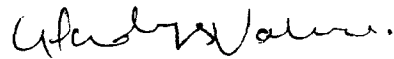
Re: Notification of Product Claims

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.

Aims
2005-6058

Almond Oil

Pure organic almond oil

For external use

Mechanically cold pressed (at a temperature below 450C) **Double filtered**

752

Apricot oil

Organic

(Prunus amarmenica)

(Non-greasy)Feeling

External use only

Face or Body message oil

Ingredients: Apricot Kernel Seed oil

754

Babchi Seeds Oil

(Psorelea Coryifolia)

Cold pressed fixed oil of Babchi Seeds

For external use only

Ingredients: Babchi oil (Psorelea Coryifolia)

756

Castor oil

Organic

For External Use

Ingredients: Cold pressed fixed oil of Ricinus communis seeds

758

Coconut oil

Organic Virgin Coconut Oil

Cold pressed virgin fixed oil of Fresh pulp of Cocos nucifera fruit

For External Use

Note: A massage oil for pitta (fire)

According to Ayurvedic theory of Tridosha Vatta(air), Pitta(fire), Kapha(water)

760

Mustard Oil (Organic)

For External use

Mustard (Brassica species) –Massage oil for hair and body massage

Ingredients: Cold pressed fixed oil of Brassica juncea seeds.

762

Neem oil

Cold pressed fixed Oil of Neem seeds Double Filtered.
Herbal Oil

For External use only

Ingredients: The fresh Neem (Azadirachita Indica)

764

SEASAME Oil

(Sesamum indicum)

For External use

Sesame oil is one of the traditional oil in Ayurveda. It is useful in abhyanga (daily body massage).

Ingredients Cold pressed fixed oil of Sesamum indicum seeds the finest Sesamum seeds are mechanically cold pressed (at a temperature below 450C)

Double filtered

766

Sunflower oil (Organic)

For external Use

Ingredients: Cold pressed fixed oil of Helianthus annus seeds

800

Blossom Hair Oil

(Hair Plus Oil)

Ingredients: Motiya (Jasmine), Amla (*Emblica officinalis*), Gotu kola (*Centella asiatica*), Brahmi (*Bacopa monnieri*), Vibhitaki (*Terminalia bellerica*), Haritaki (*Terminalia chebula*), Licorice, Musk root (*Nardostachys jatamansi*), Nutgrass (*Cyperus rotundus*), Akashvela (*Cuscuta reflexa*), Bhringaraj (*Eclipta alba*), Indrayan (*Citrullus colcyntis*) (Bitter apple), Kalkeshi (*Indigofera tinctoria*), Indian licorice (Gunja) (*Abrus precatorius*), Haridra (*Berberis asiatica*), Bala (*Sida cordifolia*), Karanj (*Pongamia glabra*), Neem (*Azadirachta indica*), Pushkara (*Inula racemosa*), Cardamom, Zedoary (*Curcuma zedoaria*) (Kachura), Manjitha (*Rubia cordifolia*), Bakuchi (*Psoralea corylifolia*) (guava), Anantmul (Indian Sarsaparilla) (*Hemidesmus indicus*), Sesame Oil (*Sesamum indicum*), Lemon (*Citrus medica*) oil.

802

Brahmi Amla

Hair Oil

Herbal Oil

External use only

All herbs used in Brahmi Amla Oil have been used in Ayurveda (science of life) for many centuries.

804

Brahmi oil

(Organic)
Herbal Oil

External use only

Ingredients: Brahmi (*Bacopa monnieri*) Plant, Based Oil Sesame Oil (Cold pressed Double filtered)

806

Flexn Oil

(Vatta Massage Oil)
Herbal Oil

For External use only

Ingredients: Boswellia Serrata (SalaiGuggul) Purified Gum Resin, Turmeric (Rhizome) oil, Ginger (Rhizome) oil, Eucalyptus (leaves) oil, Capsicum (Seed) oil, Gandapuro (*Gaultheria Fragrantissima* leaves) oil, peppermint (*Mentha Piperita* leaves) oil, Karpura (*Camphora officinarum* wood) oil, Dalchini (*Cinnamomum cassia* Bark) oil, Thymo1 (*Carum couticum* seed) oil, Sarala (Long leaved pine Oil), Sesame (Base oil) (*Sesamum indicum* seed) oil.

808

Gloris Oil

Ayurvedic Herbal Oil

Non greasy massage oil with unique natural fragrance of Rose and Sandalwood

External use only

Ingredients: For LABEL

Key Ingredients: Black mustard (*Brassica nigra*) seed, Kachura (*Curcuma zeodaria*) Rhizome, Laksha (*Lacifer lacca*) Resin, Lodhra (*Symplocos racemosa*) Bark, Jalneem (*Centella asiatica*) Plant, Ushira (*Vertiveria zizanoides*) Root, Nutmeg (*Myristica fragrans*) Seed, Licorice (*Glycyrrhiza glabra*), Neem (*Azadirachta indica*) Leaf, Vata (*Ficus bengaiensis*) Leaf, Rasna (*Pluchea lanceolata*) Leaf, Sobhanjana (*Morinja oleifera*) Seed, Agnimantha (*Premna integrifolia*) Bark, Manjishta (*Rubia cordifolia*) Root, Chandan (*Santalum album*) Almond oil (Seed), Sesame oil (Seed), Coconut oil (Fruit), Groundnut oil (Seed), Rose (Flower) and Sandalwood oil.

810

KAPHA Oil

Herbal Oil

External use only

Ingredients: Peppermint (*Mentha piperita*), Ajowan oil (*Ptychotis ajowan* oil), Nutmeg oil (*Myristica fragrans* oil), Nilgiri oil (*Eucalyptus Globulus*), Sesame oil, Sarala (Long leaved pine Oil), Karpura (*Camphora officinarum* wood) oil, Cardamom oil.

812

Maha Masha Oil

**Vatta Massage oil
Herbal Oil**

For External use only

Ingredients: Sesame oil Processed with decoction of:

Ashwagandha (*Withania somnifera*), Kachur (*Zedoaria*), Devdaru (*Cedrus deodara*), Bala (*Sida cordifolia*), Rasana (*Pluchea lanceolata*), Barley (*Hordeum vulgare*), Vidhara (*Argyreia speciosa*) Root, Kultha (*Dolichos biflorus*), Amrita (*Tinospora cordifolia*) Root, Rock mineral salt, Prasarni (*Paederia fytida*), Sowa (*Peucedanum graveolena*) fruit, Bhadangi (*Clerodendron serratum*), Vidarikand (*Ipomea digitata*) Cumin, Punarnava (*Boerhavia diffusa*), Shatavari (*Asparagus racemosus*), Black cumin, Hing (*Ferula assafoetida*), Saunf (*Foeniculum vulgare*), Piplamool (*Piper nigrum*), Chitrak (*Plumrigo zeylanica*), Jeevanti (*Leptadenia reticulata*), Cow's milk Black gram, Bael (*Aegle marmelos*), Gambhari (*Gmelina arborea*), Shyonaka (*Oroxylum indicum*), Kantkari (*Solanum virginiana*), Brahati (*Solanum anguivi*) Shalaparni (*Desmodium gangeticum*), Prishparni (*Uraria picta*), Arani (*Premna integrifolia*), Gokhru (*Tribulus terrestris*), Patala (*Stereospermum suaveolens*)

814

Maha Narayana oil

Vatta Massage oil

Herbal Oil

For External use only

Ingredients:

Sesame Seed oil (*Sesamum indicum*) Processed with decoction of

Ashwagandha (*Withania somnifera*), Brhati (*Solanum indicum*) Plant, Gokhru (*Tribulus terrestris*), Shyonak (*Oroxylum indicum*), Bala (*Sida cordifolia*), Paribhadra (*Erythrina indica*) Root, Kantakari (*Solanum xanthocarpum*), Punarnava (*Boerhaavia diffusa*) Root, Atibala (*Abutilon indicum*), Arni (*Premna integrifolia*), Prasarani, (*Paederia foetida*), Patla (*Stereospermum suaveolens*), Cow milk, Shatavari, *Asparagus racemosus*), Rasna (*Pluchea lanceolata*), Saunf (*Foeniculum vulgare*) Jeevanti (*Leptadenia reticulata*), Devdar (*Cedrus deodara*), Puvnagah (*Sarcostigma kleinii*), Shalaparni (*Hedysarum gangeticum*), Prishnparni (*Uraria picta*), Mudgaparni (*Phaseolus trilobus*), Mashparni (*Teramnus labialis*), Nagkeshar (*Mesua ferrea*) Saindhava (Rock Salt), Jatamansi (*Nardostachys jatamansi*): Rhizome, Kachur (*Curcuma Zedoaria*), Haldi (*Curcuma longa*), Haritaki (*Terminalia chebula*) Daru haridra (*Berberis aristata*) Root, Shalaki (*Boswellia*), Chandan (*Santalum album*), Pushkara (*Inula racemosa*), Varahikand (*Tacca aspera*), Cardamomum seed Manjista (*Rubia cordifolia*), Glycyrrhiza glabra, Tagar (*Valleriana wallichii*), Nagar mothan / Mustak (*Cyperus rotundus*), Tejpatra (*Cinnamomum obtusifolium*), Bhringraj (*Eclipta alba*), Ksirakakkoli (*Gymnema lactiferum*), Clove, Palash (*Butea frondosa*), Karpura (*Camphora officinarum*), Dalchini (*Cinnamomum cassia*), Kesara (*Crocus sativus*), Utpal (*Nymphaea stellata*), Bilva (*Aegle marmelos*), Vidari (*Ipomoea digitata*), Sonth (Ginger), Sitruti (*Hedychium spicatum*), Eucalyptus leaves, Mandukparni (*Centellia asiatica*)

816

Mahavishgarba Oil

Vatta Massage oil

Herbal Oil

For External use only

Ingredients: Sesame oil Processed with water decoction of:

Kanaka (*Datura alba*), Nirgundi (*Vitex Negundo*), Tumbini (*Citrullus colocynthis*), Punarvana (*Boerhaavia diffusa*), Erind (*Ricinus communis*), Ashwagandha (*Withania somnifera*), Citraka (*Plumrango geylanica*), Sobhanjana (*Moringa oleifera*), Makoi (*Solanum nigrum*), Clove (*Myrtus caryophyllus*), Haldi (*Curcuma longa*), Kantakari (*Solanum xanthocarpum*), Nimba (*Azardica indicus*), Maha nimba (*Melia azedarach*) Isvar (*Callicarpa lanata*), Bilva (*Aegle marmelos*), Nagkeshar (*Mesua ferrea*), Shyonaka (*Oroxylum indicum*), Gambhari (*Gmelina arobrea*), Patala (*Stereospermum suaveolens*), Agnimantha (*Premna integrifolia*), Salaparni (*Desmodium gangeticum*), Dalchini (*Cinnamomum cassia*), Prish parni (*Uraria picta*), Brahati (*Solanum indicum*), Gokhru (*Tribulus terrestris*), Shatavari (*Asparagus racemosus*), Kaneer (*Nerium odorum*), Sariva (*Ichnocarpus frutescens*), Mundi (*Sphaeranthus indicus*),

Vidari (verbascifolium), Arka (Calotropis Gigantea), Vacha (Acorus calamus), Kakjangha (Leele Aequata), Apamarga (Achyranthes Aspera), Bala (Sida cordifolia) Ati bala (Abutilon indicum), Nagabala (Spinosa), Maha bala (Sida cordifolia big), Meda-lakadi (Litsea Chinensis), Somavalli (Latifolium), Prasarani (Paederia fotida), Ginger (Zingiber officinale), Piper nigrum, Pippali (Piper longum), Nuxvomica, Rasana (Pluchea lancolata), Pushkara (Inula racemosa), Mothan (Cyperus rotundus), Devadaru (Cedrus deodara), Potasii carbonas, Svarijka ksara (Barilla), Rock mineral salt, Sauvarcala (Sodium chloride), Jatamansi (Nardostachys jatamansi), Vida, Udhida (Pottasium nitrate), Samudra (Sodii muras), Copper Sulphate, Katphala (Myrica Nagi), Patha (Cissampelos Pareira), Sowa/Soya (Peucedanum graveolena), Saunf (Foeniculum vulgare), Tagar (Valeriana wallichii), Bharngi (Premna herbacea), Navsar (Amonium chloride), Danti (Boliospermum montanum), Dhanvayasa (Oryza sativa), Cumin (Black cumin), Indrayan (Citrullus colocynthis)

818

Nasya Oil

Herbal Oil

For External use only

Ingredients:

Sesame oil, Tagar (Valeriana wallichii) Root , Saunf (Sweet Fellel)(Foeniculum vulgare), Jeevanta (Leptadenia reticulata), Rasna (Pluchea lanceolata), Saindwa nimak (Rock salt), Dalchini (Cinnamomum cassia), Vavding/ Vidanga (Embelia ribes), Mulethi (Licorice), Ginger (Zingiber officinale), Bhringraj (Eclipta alba), Ghee, Castor Root

820

Silfina Oil

(Pitta massage oil)

Herbal Oil

For External use only:

Ingredients: Haldi (Curcuma Longa), Karanj, Neem (Azadirachta indica), Mustard (Brassica nigra), Bakuchi (Psoralea corylifolia), Jaitoon (Olea europaea), Chakra marda (Cassia tora), Hina (Lawsonia alba), Kumkum (Crocus sativus (saffron), Chandan (Sandalwood).

822

Sirodhara oil

(Kashir Bala Oil)

Herbal Oil

For External use only

Ingredients: Sesame Oil (Sesamum indicum), Khareti (sida cordifolia) Camphor Oil (Camphora officinarum), milk fat.

824

Wholy

Oil Bath
Ayurvedic
whole body herbal massage Oil

For External use only

Ingredients:

Sandal wood (*Santalum album*), Lakh (*Laccifera lacca*), Bala (*Sida cordifolia*) Plant, Khas (*Andropogon muricatus*), Mulethi (Licorice) Root, Saunf (Sweet Fellel)(*Foeniculum vulgare*), Kutki (*Picrohiza kurroa*) Rhizome, Devdaru (*Cedrus deodra*) Heart wood, Haldi (*Curcuma longa*), Manjishta (*Rubia cordifolia*), Sugandbala ((*Valeriana wallichii*), Ashwagandha (*Withania somnifera*), Daru haridra (*Berberis aristata*), Nagar mothan (*Cyperus rotundus*), Murva, Elachi (*Elettaria cardamomum*), Dalchini (*Cinnamomum cassia*)(Cinnamon), Nagkesar (*Mesua ferrea*) Flower, Rasna (*Pluchea lanceolata*) Leaves, Ajowain (*carum couticum*): Seeds, Karpura ((*Camphora officinarum*) wood, Sariva (*Ichnocarpus frutescens*), Giloy / Guduchi (*Tinospora cordifolia*): Stem, Kachura (*Curcuma zedoaria*) Tubers, Shatavari (*Asparagus racemosus*): Root, Bata tree (Batvariksh), Gultheria oil, Peppermint (*Mentha piperita*), Almond oil, Bakuchi (*Cyamopsis psoralioides*) Seeds, Panwar beej, Lodhra (*Symplocos racemosa*) Bark, Jatamansi (*Nardostachys jatamansi*), Sarson oil, Til tail, Tulsi (*Ocimom sanctum*), Neem (*Azadirachta indica*), Chharila (*Parmelia Perlata*), Padmakh, Eucalyptus oil, Jasmine, Laung / Clove (*Myrtus caryophyllus*), Tejpatra (*Cinnamom tamala*) Bark, Shalaki (*Boswellia serrata*) Gum resin, Sowa/Soya (*Peucedanum graveolena*) fruit, Karanj (*Pongamia glabra*) Seeds, alakanguni (*Celastrus paniculata*) Seeds, Apricot oil, Tagar (*Valeriana wallichii*), Baer di chal, Khadira, Nutmeg (*Myristica fragrans*), Lemon

826

WONDRUFF OIL

Non greasy
Herbal Oil

External use only

Each 10 ml contains oily extract of:

Ingredients: Amaravela (*Cuscuta reflexa*), Brungraj (*Eclipta alba*), Amla (*Phyllanthus Amblica*), Brahmi (*Herpestis monniera*), Mehndi (*Lawsonia album*), Haridra (*Berberis aristata*), Bahera (*Terminalia belberica*), Chakra marda (*Casia tora*), Sandalwood Oil (*Chandana*), Almond oil (*prunella amygdalus*), Citrus bergamia Oil, Coconut oil (Oil of *Cocoes Nucifera*), Mineral oil.