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December 30, 1999

VIA HAND DELIVERY

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

Dear Madam or Sir:

This notification is being filed pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 101.93. Uniweal, Ltd., Room 803, Corn Yan Center, 3 Jupiter Street, North Point, Hong Kong, People's Republic of China, plans to market a dietary supplement bearing the following statements on the label and/or in the labeling.

Name of Supplement: CEBALENITE™

Dietary Ingredients: Rehmannia (Di-Huang) (root)
 Chinese Yam (Shan-Yao) (root)
 Japanese Apricot (Wu-Mei) (fruit)
 Kudzu (root)
 Lycium Berries (Go-Qi-Zi) (fruit)
 Alisma (Ze-Xie) (root)
 Chinese Goldthread (Huang-Lian) (root)
 White Mulberry (Sang-Ye) (leaf)
 Lotus (leaf)
 Cinnamon, cassia (twig)
 Ginseng, oriental (root)

Structure/Function Statements:

1. This product supports the immune system.

LET4855

97S - 0162

Philadelphia	Washington	New York	Los Angeles	Miami	Harrisburg	Pittsburgh	Princeton
	London	Brussels	Frankfurt	Tokyo	Singapore	Jakarta	

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2. This product promotes vitality, mental endurance and well-being.
3. This product helps to promote healthy endocrine function.

The effects on the structure and function of the body as stated above arise from the proprietary blend of dietary ingredients present in CEBALENITE™ (as listed above).

Summary of Substantiation:

The claims “support the immune system,” “helps to promote healthy endocrine function,” and “promotes vitality, mental endurance and well-being” for the proprietary blend of dietary ingredients in CEBALENITE™ are based on, and supported by, reference to authoritative scientific literature, and the existence of previously notified/permitted claims for selected ingredients in CEBALENITE™.

The Pharmacopoeia of the People’s Republic of China,^{1/} which is approved by the Ministry of Public Health of the People’s Republic of China, summarizes the special manufacturing procedures used to produce the dietary ingredients in CEBALENITE™ and the actions and indications associated with the endocrine and immune systems and the feelings of energy and vitality for these dietary ingredients. In addition, the Physicians Desk Reference for Herbal Medicines^{2/} states information about the effects of several of the dietary ingredients in CEBALENITE™ on the endocrine and immune systems and energy level, and provides information about the associated indications for use.^{3/} Specifically, the Pharmacopoeia of the People’s Republic of China states the following actions and indications for the component ingredients of CEBALENITE™:

1/ The Pharmacopoeia Commission of PRC, Pharmacopoeia of the People’s Republic of China (Chemical Industry Press, English ed. 1997) (Chinese ed. 1995) (excerpts attached).

2/ Physicians Desk Reference for Herbal Medicines (Thomas Fleming, RPh., et al., eds., Medical Economics Co. 1998) (hereinafter “PDR Herbal Medicines”) (excerpts attached).

3/ See, e.g., id. at 809-10 (wild yam for gallbladder).

- Rehmannia (Di-Huang) (root)
Action: removing or reducing “heat” and promoting the production of body fluid; Indication: febrile diseases, impairment or deficiency of “yin,” and diabetes caused by internal “heat.”^{4/}
- Chinese Yam (Shan-Yao) (root)
Action: “replenish the spleen and stomach, to promote fluid secretion”;
Indications: “[a]norexia and chronic diarrhea due to diminished function of the spleen . . . excessive leukorrhea, frequency of urination or diabetes due to deficiency condition of the kidney.”^{5/}
- Japanese Apricot (Wu-Mei) (fruit)
Action: “relieve diarrhea by astringing the intestines, to promote the production of body fluid”; Indication: persistent cough, chronic dysentery and diarrhea.^{6/}
- Kudzu (root)
Action: relieves fever, promotes the production of bodily fluid and arrests diarrhea; Indications: fever, headache, stiffness, diabetes, and acute dysentery or diarrhea.^{7/}
- Lycium Berries (Go-Qi-Zi) (fruit)
Action: “[t]o benefit the liver and kidney, to replenish vital essence”;
Indications: “[g]eneral debility with deficiency of vital essence . . . dizziness and tinnitus; diabetes caused by internal heat; [and] anemia.”^{8/}

4/ Pharmacopoeia of the People’s Republic of China, supra note 1, at 166 (italics omitted).

5/ Id. at 192 (italics omitted); see PDR for Herbal Medicines, supra note 2, at 809-10 (actions and indications for “wild yam”).

6/ Pharmacopoeia of the People’s Republic of China, supra note 1, at 72.

7/ Id. at 164-65.

8/ Id. at 70 (italics omitted).

- Alisma (Ze-Xie), Alisma (root)
Action: causes diuresis and removes “damp-heat”; Indications: “[e]dema with oliguria; diarrhea with diminished discharge of urine; [and] vertigo due to retention of fluid.”^{9/}
- Chinese Goldthread (Huang-Lian) (root)
Action: “[t]o remove damp-heat, quench fire and counteract toxicity”;
Indications: “[a]ttack of damp-heat . . . ; high fever accompanied by impairment of consciousness; . . . spitting of blood and epistaxis caused by heat in the blood; . . . diabetes.”^{10/}
- White Mulberry (Sang-Ye) (leaf)
Action: “[t]o dispel wind-heat and to remove heat from the lung, to subdue hyperactivity of the liver”; Indications: “[u]pper respiratory infection, heat in the lung with dry cough; [and] dizziness [and/or] headache.”^{11/}
- Lotus (leaf)
Action: “[t]o relieve summer-heat, to invigorate the spleen function . . . and arrest bleeding”; Indications: “summer-heat . . . ; diarrhea caused by summer-damp or hypofunction of the spleen; spitting of blood, epistaxis, [or] hematochezia.”^{12/}

^{9/} Id. at 181 (italics omitted); see PDR for Herbal Medicines, supra note 2, at 623 (Alisma Plantago-aquatica, Water Plantain).

^{10/} Pharmacopoeia of the People’s Republic of China, supra note 1, at 187-88 (italics omitted); see PDR for Herbal Medicines, supra note 2, at 774-75 (“used in digestive disorders”).

^{11/} Pharmacopoeia of the People’s Republic of China, supra note 1, at 50; see PDR for Herbal Medicines, supra note 2, at 980 (black mulberry, which is indicated as mild laxative and for treating respiratory catarrh, which is inflammation of the mucous membranes).

^{12/} Pharmacopoeia of the People’s Republic of China, supra note 1, at 50 (italics omitted); see PDR for Herbal Medicines, supra note 2, at 990-91 (indicated for digestive disorders, including diarrhea and as astringent for bleeding).

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- Cinnamon, cassia (twig)
Action: induces perspiration, reinforces “yang,” relieves palpitations, and promotes the “descending of qi”; Indications: common cold, epigastric pain, arthralgias, edema, cardiac palpitations, gastrointestinal neurosis.^{13/}
- Ginseng, oriental (root)
Action: “reinforce the vital energy, to remedy collapse and restore the normal pulse, to benefit the spleen and lung, to promote the production of body fluid, and to calm the nerves”; Indications: “[p]rostration with impending collapse,” “diminished function of the spleen,” “thirst due to impairment of body fluid, of diabetes caused by internal heat; general weakness with irritability and insomnia in chronic diseases.”^{14/}

Moreover, the Food and Drug Administration (“FDA”) has previously been notified of, and has permitted, claims similar to, or related to, the proposed claims for certain of the ingredients in CEBALENITE™. Specifically, companies have notified FDA and FDA has permitted the following structure/function claims for Goldthread:

- “for immune system support . . . adds powerful defense to your immune system”^{15/}; and
- “contains beneficial alkaloids that support the body’s natural defense.”^{16/}

^{13/} Pharmacopoeia of the People’s Republic of China, supra note 1, at 177 (italics omitted); see PDR for Herbal Medicines, supra note 2, at 750 (antibacterial effects; improves immunity; indicated for digestive complaints, common cold, rheumatic conditions and to stabilize immunity).

^{14/} Pharmacopoeia of the People’s Republic of China, supra note 1, at 151-52 (italics omitted); see PDR for Herbal Medicines, supra note 2, at 1009 (indicated for lack of stamina, for invigoration and fortification).

^{15/} Terese Maltzman, Ph.D., Amrion, Inc., Notification Letter to FDA (Feb. 22, 1999) (Echinacea-Goldthread supplement claim) (copy attached).

^{16/} Dietary Supplement Structure/Function Claims: Performance Labs, F-D-C Rep. (“The Tan Sheet”), Apr. 19, 1999, at 23 (copy attached).

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FDA received notification for and permitted the following structure/function claims for Ginseng:

- “[e]nhances mental endurance and vitality”;^{17/}
- “[p]romotes vitality and well-being”;^{18/}
- “[t]o maximize performance, boost energy, and combat fatigue and stress”;^{19/}
and
- “enhanc[es] endurance and adrenal gland health.”^{20/}

For the other dietary ingredients in CEBALENITE™, notified and permitted structure/function claims include the following:

- for Rehmannia and Alisma: “beneficial effects on the . . . endocrine system”^{21/};
and

^{17/} The News This Week: Dietary Supplement Statements, F-D-C Rep. (“The Tan Sheet”), Nov. 18, 1996 (copy attached).

^{18/} Heidi Horn, Perrigo Company, Notification Letter to FDA (Mar. 23, 1999) (copy attached).

^{19/} Thilo Koeler, Dietetics Pharma Int’l, Inc., Notification Letter to FDA (May 12, 1999) (claim attributed to toxic containing ginseng and other herbs plus vitamins) (copy attached).

^{20/} Dietary Supplement Structure/Function Claims: Pure Encapsulations, F-D-C Rep. (“The Tan Sheet”), Feb. 1, 1999, at 12 (copy attached).

^{21/} Daqun Zhang, Ph.D., Nature’s Essence, Notification Letter to FDA (Apr. 9, 1999) (copy attached).

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- for Chinese Yam and Rehmannia: “traditionally used to tonify kidney “yin” and are associated with health and vitality,” “support adrenal and immune function.”^{22/}

Accordingly, the proposed claims:

- This product supports the immune system.
- This product promotes vitality, mental endurance and well-being.
- This product helps to promote healthy endocrine function.

are proper and supportable for the proprietary blend in CEBALENITE™.

The undersigned certifies that the information presented and contained in this notification is complete and accurate, and that Uniweal, Ltd. has substantiation that the structure/function statement is truthful and not misleading.

Sincerely,



Stephen Paul Mahinka
Counsel for Uniweal, Ltd.

Enclosures

^{22/} Dietary Supplement Structure/Function Claims: Metagenics, F-D-C Rep. (“The Tan Sheet”), June 28, 1999, at 17 (adrenal support dietary supplement containing, among other things, Chinese Yam and Rehmannia) (copy attached).

PHARMACOPOEIA OF THE PEOPLE'S REPUBLIC OF CHINA

(English Edition 1997)

Volume I

Compiled by The Pharmacopoeia Commission of PRC

CHEMICAL INDUSTRY PRESS
BEIJING, CHINA

PHARMACOPOEIA OF THE PEOPLE'S REPUBLIC OF CHINA

(English Edition 1997)

Volume I

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MONOGRAPHS

PART I

Chinese Materia Medica,
Oil, Fats, etc.

filled with starch granules.

Action To dissolve lumps and cause subsidence of swelling.

Indications Tuberculosis of lymph nodes without ulceration.

Usage and dosage 15–30 g; up to 120 g when used alone or as simple preparation.

Storage preserve in a ventilated and dry place, protected from moth.

Radix Rehmanniae

(地黃, Dihuang)

Rehmannia Root

Rehmannia Root is the fresh or dried root tuber of *Rehmannia glutinosa* Libosch. (Fam. Scrophulariaceae). The drug is collected in autumn, removed from root stock, rootlet and soil, used either in fresh state or baked to almost dry. The former is known as "Xian Dihuang" (Fresh Rehmannia Root) and the latter is known as "Sheng Dishuang" (Unprocessed Rehmannia Root).

Description *Xian Dihuang* Fusiform or spat-shaped, 8–24 cm long, 2–9 cm in diameter, the outer bark thin, externally pale reddish-yellow, with curved longitudinal wrinkles, bud scars, elongated transverse lenticels and irregular scars. Texture fleshy, easily broken, yellowish-white, orange-red oil dots scattered in bark, fracture yellowish-white, with vessels arranged radially in wood. Odour, slight; taste, slightly sweet and bitterish.

Sheng Dihuang Mostly in irregular masses or oblong, swollen in the centre, slightly tapering at both ends, 6–12 cm long, 3–6 cm in diameter. Some small, slit-shaped, slightly compressed or twisted. Externally brownish-black or brownish-greyish, heavily shrunken, with irregular transverse wavy lines. Texture heavy, soft and tenacious, uneasily broken, fracture brownish-black or jet-black, lustrous, viscous, Odourless; taste, slightly sweet.

Identification (1) Transverse section: Cork consisting of several layers of cells. In cortex parenchymatous cells loosely arranged; scattered with more secretory cells, containing orange-yellow oil droplets; stone cells occasionally found. Phloem relatively broad, secretory cells less. Cambium in a ring. Xylem rays broad, vessels sparse, arranged radially.

Powder of Sheng Dihuang: Dark brown. Cork cells brownish, subrectangular in lateral view, regularly arranged. Parenchymatous cells subrounded, containing subrounded nuclei. Secretory cells mostly similar to ordinary parenchymatous cells in shape, containing orange or orange-red oil droplets. Bordered pitted and reticulate vessels up to about 92 μm in diameter.

(2) To 2 g of the powder add 20 ml of methanol, heat under reflux on water bath for 1 hour, cool, filter, distill the filtrate to recover methanol, until 5 ml of filtrate is remained, use the filtrate as the test solution. Dissolve catalpol CRS in methanol to produce a solution containing 0.5 mg per ml used as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B) using silica gel G as the coating substance and a mixture of chloroform-methanol-water (70:30:5) as the mobile phase. Apply separately to the plate 5 μl of each of the above two solutions.

After developing and removal of the plate, dry it in air, spray with anisaldehyde TS, heat a 105°C for 5 minutes. A spot in the chromatogram obtained from the test solution corresponds in colour and position to spot in the chromatogram obtained from the reference solution.

Total ash Not more than 6.0% (Appendix IX K).

Acid-insoluble ash Not more than 2.0% (Appendix IX K).

Water soluble extractives Carry out the method for determination of extractives-cold maceration method (Appendix X A), not less than 65.0%.

Processing Eliminate foreign matter, wash clean, cover to soften, cut into thick slices, and dry.

Action Fresh Radix Rehmanniae: To remove heat and promote the production of body fluid, to reduce heat in blood, and to arrest bleeding.

Radix Rehmanniae (unprocessed): To reduce heat in blood, to nourish yin and promote the production of body fluid.

Indications Fresh Radix Rehmanniae: Impairment of yin in febrile diseases marked by deep red tongue and thirst; skin eruption and maculation; spitting of blood, epistaxis; sore throat.

Radix Rehmanniae (unprepared): Febrile diseases with deep red tongue and thirst; deficiency of yin with internal heat; consumptive fever; diabetes caused by internal heat; spitting of blood, epistaxis; skin eruption and maculation.

Usage and dosage Fresh Radix Rehmanniae: 12–30 g.

Radix Rehmanniae (unprocessed): 9–15 g.

Storage Embed Fresh Rehmannia Root in sand and protect from freezing; unprocessed Rehmannia Root is preserved in a ventilated dry place, protected from mould and moth.

Radix Rehmanniae Preparata

(熟地黃, Shudihuang)

Prepared Rehmannia Root

The drug is the processed Radix Rehmanniae.

Procedure (1) Stew the clean Radix Rehmanniae as described under the method for stewing with wine (Appendix II D) until the wine is absorbed entirely, take out, dry in the sun until the mucilage in bark is slightly dried, cut into thick slices or pieces, and dry thoroughly.

To each 100 kg of Radix Rehmanniae add 30–50 kg of yellow rice wine.

(2) Steam the clean Radix Rehmanniae as described under the method for steaming (Appendix II D) until it becomes blackish and shiny, take out, dry in the sun to be eighty percent dried, cut into thick slices or pieces, and dry thoroughly.

Description Occurring in irregular slices and pieces, broken lumps, varying in size and thickness. Externally jet-black, lustrous, more sticky. Texture soft and flexible, uneasily broken, fracture jet-black, lustrous. Odourless; taste, sweet.

Identification To 1 g of the powder add 10 ml of ethanol, macerate for 24 hours, filter, and use the filtrate as the test solution. Dissolve 5-(hydroxy methyl) furfural CRS in ethanol to produce a solution containing 0.5 mg per ml as the reference solution. Carry out the method for thin-layer chromatography (Appendix VI B), using silica gel GF₂₅₄ as the coating substance and petroleum ether (60–90°C)-

dinitrophenyl hydrazine TS, the colour of the spot turns to orange-red gradually on standing.

Total ash Not more than 4.0% (Appendix [X] K).

Processing *Rhizoma Cyperi* Remove fibrous matter and foreign matter, pound to pieces or cut into thin slices.

Rhizoma Cyperi (processed with vinegar) Stir-fry the pieces or slices of *Rhizoma Cyperi* as described under the method for stir-frying with vinegar (Appendix [I] D) to dryness.

Action To remove stagnation of *qi*, regulate menstruation and relieve pain.

Indications Stagnation of the *liver qi* characterized by distending pain in the chest, hypochondria and epigastrium, indigestion, feeling of stuffiness in the chest and epigastrium, abdominal colic, distending pain in the breast, menstrual disorders, amenorrhea or dysmenorrhea.

Usage and dosage 6~9 g.

Storage Preserve in a cool and dry place, protected from moth.

Rhizoma Dioscoreae

(山药, Shanyao)

Common Yam Rhizome

Common Yam Rhizome is the dried rhizome of *Dioscorea opposita* Thunb. (Fam. Dioscoreaceae). The drug is collected in winter when the stem and leaf are withered, deprived of root stock, washed clean and deprived of outer bark and fibrous root, fumigated with sulfur, and then dried. Otherwise thick large straight and dried rhizome is sorted, soaked in clean water until the central portion of the drug gets wet and softened thoroughly, then fumigated with sulfur, cut two ends to smooth plane and rubbed on a board to become cylindrical in shape, dried in the sun and finally polished. It is known as "Guang Shanyao" (Polished Common Yam Rhizome).

Description Subcylindrical, curved or somewhat flattened, 15~30 cm long, 1.5~6 cm in diameter. Externally yellowish-white or pale yellow, longitudinally furrowed and wrinkled, and bearing fibrous root scars, with occasional patches of brownish cork. Texture heavy, compact and tough; uneasily broken, fracture white and starchy. Odourless; taste, weak, acidulous, and viscous when chewed. Guang Shaoyao cylindrical, the two ends even, 9~18 cm long, 1.5~3 cm in diameter, externally smooth, white or yellowish-white.

Identification Powder: Whitish. Simple starch granules compressed-ovoid, subrounded, deltoid-ovoid or oblong, 8~35 μm in diameter, hilum pointed, V-shaped, X-shaped or shortly cleft, striations visible. Compound starch granules less common, usually consisting of 2~3 granules. Mucilage cells containing raphides of calcium oxalate, up to 240 μm long and needle crystals 2~5 μm wide. Bordered-pitted, reticulate, spiral and annular vessels, 12~48 μm in diameter.

Processing *Rhizoma Dioscoreae* Eliminate foreign matter, grade according to size, soak and soften thoroughly, cut into thicker slices, and dry.

Rhizoma Dioscoreae (stir-fried with bran) Stir-fry the slices of *Rhizoma Dioscoreae* as described under the method for stir-frying with bran (Appendix [I] D) to yellowish.

Action To replenish the *spleen* and stomach, to promote fluid secretion and benefit the *lung*, and to strengthen the *kidney* and restrain seminal discharge.

Rhizoma Dioscoreae (stir-fried with bran): To replenish the *spleen* and promote the stomach function.

Indications Anorexia and chronic diarrhea due to diminished function of the *spleen*; cough and dyspnea due to diminished function of the *lung*; seminal emission, excessive leukorrhea, frequency of urination or diabetes due to deficiency condition of the *kidney*.

Rhizoma Dioscoreae (stir-fried with bran): Diminished function of the *spleen* with anorexia, diarrhea and excessive leukorrhea.

Usage and dosage 15~30 g.

Storage Preserve in a ventilated and dry place, protected from moth.

Rhizoma Dioscoreae Hypoglaucae

(粉萆薢, Fenbixie)

Hypoglaucous Collett Yam Rhizome

Hypoglaucous Collett Yam Rhizome is the dried rhizome of *Dioscorea hypoglauca* Palibin (Fam. Dioscoreaceae). The drug is collected in autumn and winter, removed from the fibrous root, washed clean, cut into slice, and dried in the sun.

Description Irregularly thin slices, border uneven, varying in size, about 0.5 mm thick, some with brownish-black or greyish-brown outer bark. Slices yellowish-white or pale greyish-brown, vascular bundles scattered. Texture loose, slightly elastic. Odour, weak; taste, pungent and slightly bitter.

Identification (1) Transverse section: Suberized cells of more layers. Cortex narrow, cells tangentially elongated, walls slightly thickened, pits distinct, mucilage cells scattered, containing raphides of calcium oxalate. Collateral and amphivasal vascular bundles scattered in stele, parenchymatous cells walls slightly thickened, with pits, containing starch granules.

Powder: Yellowish-white. Simple starch granules rounded, ovoid or long-elliptical, 5~32 μm in diameter, up to 40 μm long, hilum pointed or cleft-like, compound granules less, mostly composed of two components. Sclerenchymatous cells abundant, walls lignified, pits distinct, some similar to stone cells, polygonal, fusiform or sub-rectangular, 40~80 μm in diameter, up to 224 μm long. Raphids of calcium oxalate 64~84 μm long.

(2) Macerate 10 g of the powder in 100 ml of water overnight, heat on a water bath at 60°C for 10 minutes, filter while hot. Measure the filtrate, each of 2 ml, to two test tubes. To one tube add 2 ml of sodium hydroxide TS, and to another tube add 2 ml of hydrochloric acid solution (1~20), stopper well, shake vigorously for 1 minute, the foam produced in the alkaline solution is several times higher than that produced in the acid solution.

Action To remove turbid *damp*, and to relieve rheumatic conditions.

Indications Chyluria, turbid urine mixed with whitish substance or whitish discharge from urethra, excessive leukor-

alba L. (Fam. Moraceae). The drug is collected in April to June when the fruit turns red, dried in the sun, or dried after steaming briefly.

Description Collective fruit, aggregated by many small achenes, fruit-spike oblong, 1–2 cm long, 5–8 mm in diameter. Yellowish-brown, brownish-red to dark purple, with a short fruit stalk. Achene ovoid, slightly flattened, about 2 mm long and 1 mm wide, with 4 fleshy perianth-segments. Odour, slightly; taste, slightly sour and sweet.

Extractives Carry out the hot extraction method as described under the determination of ethanolsoluble extractive (Appendix X A), using 85% ethanol as the solvent, not less than 15.0%.

Action To nourish *yin* and blood and promote the production of body fluid.

Indications Vertigo and tinnitus, palpitation, insomnia, premature greying of hair and beard; thirst due to impairment of body fluid; diabetes caused by internal *heat*; constipation due to *deficiency of blood*.

Usage and dosage 9–15 g.

Storage Preserve in a ventilated and dry place, protected from moth.

Fructus Mume

(乌梅, Wumei)

Smoked Plum

Smoked Plum is the almost ripe and dried fruit of *Prunus mume* (Sieb.) Sieb. et zucc. (Fam. Rosaceae). The drug is collected in summer when almost ripe, baked at a low temperature, and covered until turns to black in colour.

Description Subspheroidal or flattened-spheroidal, 1.5–3 cm in diameter. Externally black or brownish-black, shrunken, with a rounded fruit stalk scar at the base. Kern hard, ellipsoidal, brownish-yellow, with dented spots on surface; seeds flattened-ovoid, pale yellow. Odour, slight; taste, extremely sour.

Assay Weigh accurately about 4 g of the most coarse powder [perform a determination of water (Appendix X H, method 2)] in a conical flask, add 100 ml of water, accurately measured, heat under reflux for 4 hours, cool, filter, discard the initial filtrate, collect the successive filtrate. To 20 ml of the successive filtrate, accurately measured, add water to 80 ml. Carry out the method for potentiometric titration (Appendix VII A), titrate with sodium hydroxide (0.1 mol/L) VS. Each ml of sodium hydroxide (0.1 mol/L) VS is equivalent to 6.404 mg of $C_6H_4O_7$. It contains not less than 15.0% of organic acids, calculated as citric acid ($C_6H_4O_7$), on the dried basis.

Processing *Fructus Mume* Eliminate foreign matter, wash clean, and dry.

Pulp of Fructus Mume Soften the clean Fructus Mume with water or by steaming, removed from kernels.

Fructus Mume (carbonized) Stir-fry the clean Fructus Mume as described under the method of carbonizing by stir-frying (Appendix II D) until pericarp and pulp bulged.

Action To arrest persistent cough, to relieve diarrhea by astringing the intestines, to promote the production of

body fluid, and to relieve colic caused by ascaris.

Indications Persistent cough in *deficiency syndromes of the lung*; chronic dysentery and diarrhea; thirst in consumptive diseases; colic and vomiting caused by ascaris, biliary ascariasis.

Usage and dosage 6–12 g.

Storage Preserve in a cool and dry place, protected from moisture.

Fructus Oryzae Germinatus

(稻芽, Daoya)

Rice-grain Sprout

Rice-grain Sprout is the dried germinated ripe fruit of *Oryza sativa* L. (Fam. Graminae). The fruit is soaked in water at an appropriate temperature and moisture, then dried when the fibrous roots grow to about 1 cm long.

Description Flattened-elliptical, both apexes acuminate, 7–9 mm long, about 3 mm in diameter. Lemma yellow, bearing white pubescences and 5 veins. One apex with 2 symmetrical, white strip-shaped lodicules, 2–3 mm long, from the inner side of one lodicule spreading 1–3 curved fibrous roots, 0.5–1.2 cm long. Texture hard, fracture white and starchy. Odourless; taste, weak.

Budding rate Carry out the method for Sampling of crude drugs (Appendix II A), taking two samples from 10 g of the drug diagonally to count the germinative grains and the total grains then budding rate. The budding rate is not less than 85%.

Processing *Fructus Oryzae Germinatus* Eliminate foreign matter.

Fructus Oryzae Germinatus (stir-fried) Stir-fry the clean *Fructus Oryzae Germinatus* as described under the method for simple stir-frying (Appendix II D) until a dark yellow colour is produced.

Fructus Oryzae Germinatus (charred) Stir-fry the clean *Fructus Oryzae Germinatus* as described under the method for simple stir-frying (Appendix II D) until it becomes charred yellow colour.

Action To promote digestion, invigorate the function of the *spleen* and improve appetite.

Fructus Oryzae Germinatus (stir-fried): To promote digestion.

Fructus Oryzae Germinatus (charred): To remove the retained food.

Indications Retention of undigested food with abdominal distension and foul breath; weakness of the *spleen* and the stomach with anorexia.

Fructus Oryzae Germinatus (stir-fried): Anorexia.

Fructus Oryzae Germinatus (charred): Retention of undigested food.

Usage and dosage 9–15 g.

Storage Preserve in a ventilated and dry place, protected from moth.

Processing Eliminate foreign matter, wash, macerate, soften thoroughly, cut into thick slices or pieces, and dry.

Action To counteract toxicity, to cure carbuncles, and to relax bowels.

Indications Lymphadenitis, carbuncles, urticaria with itching; constipation; hyperlipemia.

Usage and dosage 6~12 g.

Storage Preserve in a dry place, protected from moth.

Radix Polygoni Multiflori Preparata (制何首乌, Zhiheshouwu)

Prepared FLeecflower Root

The drug is the processed Radix Polygoni Multiflori.

Procedure Mix the slices or pieces of Radix Polygoni Multiflori thoroughly with black bean juice. Carry out the stewing method (Appendix II D) in a suitable non-ferrous container until the juice is exhausted or carry out the steaming method (Appendix II D), steam it alone or steam it after being mixed with black bean juice to a brown colour on all sides, dry it in the sun to partial dryness, then cut into slices and dry.

For each 100 kg of slice (piece) of Radix Polygoni Multiflori use 10 kg of black bean.

Preparation of black bean juice: Boil 10 kg of black bean in a sufficient quantity of water for about 4 hours and stew to get about 15 kg of juice. Boil the bean residue again in water for about 3 hours and stew to get about 10 kg of juice. Combine to get about 25 kg of the black bean juice.

Description Irregularly shrunken pieces or slices, about 1 cm thick. Externally dark brown or brown, uneven. Texture hard, fracture horny, brown or black. Odour slight, taste, slightly sweet, bitter and astringent.

Identification Complies with test (2) for Identification described under Radix Polygoni Multiflori.

Action To replenish the liver and the kidney with vital essence and blood, to blacken the hair, and to strengthen the tendons and bones.

Indications Anemia; dizziness and tinnitus; premature greying of the hair and beard; soreness and weakness of the loins and the knees; abnormal uterine bleeding and excessive leukorrhea; general debility in chronic malaria; hyperlipemia.

Usage and dosage As described under Radix Polygoni Multiflori.

Storage As described under Radix Polygoni Multiflori.

Radix Pseudostellariae (太子参, Taizishen)

Heterophylly Falsestarwort Root

Heterophylly Falsestarwort Root is the dried root tuber of *Pseudostellaria heterophylla* (Miq.) Pax et Hoffm. (Fam. Caryophyllaceae). The drug is collected in autumn when stem and leaves mostly withered, washed clean, removed from

rootlet, either treated with boiling water for a moment and dried in the sun, or dried in the sun directly.

Description Slenderly fusiform or spat-shaped, slightly curved, 3~10 cm long, 2~6 mm in diameter. Root stock marked with stem scars, externally yellowish-white, relatively smooth but slightly wrinkled longitudinally, with rootlet scars at a dent. Texture hard and fragile, fracture even, yellowish-white and horny, or whitish and starchy. Odour, slight; taste, sweetish.

Identification (1) Transverse section: Cork consisting of 2~4 rows of subsquare cells. Cortex thin, only consisting of several rows of parenchymatous cells, elongated tangentially. Phloem narrow, with broad rays. Cambium in a ring. The majority of root occupied by xylem, vessels sparse and arranged radially, primary xylem occurring triarch to tetra-arch. Parenchymatous cells packed with starch granules and clusters of calcium oxalate.

(2) Macerate warmly 1 g of the powder in 10 ml of methanol, shake for 30 minutes, filter, use filtrate as the test solution. Prepare a solution of Radix Pseudostellariae reference drug in the same manner as the reference drug solution. Carry out the method for thin layer chromatography (Appendix VI B) using silica gel G containing sodium carboxymethyl cellulose as the coating substance and *n*-butanol-glacial acetic acid-water (4:1:1) as the mobile phase. Apply separately 1 μ l of each of the two solutions, to the plate. After developing in a chamber pre-equilibrated with mobile phase for 15 minutes and removal of the plate, dry it in air, spray with 0.2% ninhydrin ethanol solution, heat at 105°C until the colour spots appear clearly. A spot in the chromatogram obtained from the test solution corresponds in colour and position to the spot in the chromatogram obtained from the reference drug solution.

Action To replenish *qi* and invigorate the spleen function, and to promote fluid secretion and moisten the lung.

Indications Hypofunction of the spleen with lassitude and anorexia; debility and deficiency of *qi* and *yin* marked by spontaneous sweating and thirst during convalescence dry cough due to dryness of the lung.

Usage and dosage 9~30 g.

Storage Preserve in a ventilated dry place, protected from moisture and moth.

Radix Puerariae

(葛根, Gegen) ✓

Kudzuvine Root

Kudzuvine Root is the dried root of *Pueraria lobata* (Willd.) Ohwi or *Pueraria thomsonii* Benth. (Fam. Leguminosae). The drug is collected in autumn and winter. The root of *Pueraria lobata* (Willd.) Ohwi is often cut into thick slices or pieces when fresh, and dried. The root of *Pueraria thomsonii* Benth. known as "Star", Radix Puerariae, is often removed from the outer bark, fumigated with sulfur, dried for a while, then cut into sections, or cut again longitudinally into two pieces, and dried.

Description Root of *Pueraria lobata* In rectangular thick slices cut longitudinally or small square pieces, 5~35 cm

long, 0.5–1 cm thick. The outer bark pale brown, with longitudinal wrinkles, rough, cut surface yellowish-white, striations indistinct. Texture pliable and strongly fibrous. Odourless, taste, slightly sweetish.

Root of *Pueraria thomsonii* Cylindrical, subfusiform or semicylindrical, 12–15 cm long, 4–8 cm in diameter, some longitudinally or obliquely cut thick slices, varying in size. Externally yellowish-white or pale brown, or greyish-brown when unpeeled. Transversely cut surface showing pale brown concentric rings formed by fibres, longitudinally cut surface showing several longitudinal striations formed by fibres. Heavy, texture hard and starchy.

Identification (1) Powder: Pale brown, yellowish-white or pale yellow. Starch granules abundant, simple granules spheroidal, semirounded or polygonal, 3–37 μm in diameter, hilum pointed, cleft or stellate, compound granules of 2–10 components. Fibres mostly in bundles, walls thickened and lignified, surrounded by parenchymatous cells mostly containing prisms of calcium oxalate, forming crystal fibres, crystal cells, with lignified and thickened walls. Stone cells infrequently visible, subrounded or polygonal, 38–70 μm in diameter. Bordered pitted vessels relatively large, pits hexagonal or elliptical, arranged very densely.

(2) Macerate 0.8 g of the powder in 10 ml of methanol for 2 hours, filter and evaporate the filtrate to dryness. Dissolve the residue in 0.5 ml of methanol as test solution. Dissolve puerarin CRS in methanol to produce a solution containing 1 mg per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B), using silica gel H containing sodium carboxymethylcellulose as the coating substance and chloroform-methanol-water (7:2.5:0.25) as the mobile phase. Apply in strip separately to the plate 10 μl of each of the two solutions. After developing and removal of the plate, dry it in air and examine under ultra-violet light (365 nm). The fluorescent strip in the chromatogram obtained with the test solution corresponds in position and colour to the fluorescent strip in the chromatogram obtained with the reference solution.

Water Carry out the method for the determination of water (Appendix IX H, method 1), not more than 14.0%.

Total ash *Radix Puerariae Lobatae*: Not more than 7.0%; *Radix Puerariae Thomsonii*: Not more than 5.0% (Appendix IX K).

Processing Eliminate foreign matter, wash clean, soften thoroughly, cut into thick pieces, and dry in the sun.

Action To relieve fever, to promote the production of body fluid, to facilitate eruption, and to arrest diarrhea.

Indications Fever, headache and stiffness of the nape in exogenous affections, thirst, diabetes, measles with inadequate eruption, acute dysentery or diarrhea, stiff and painful nape in hypertension.

Usage and dosage 9–15 g.

Storage Preserve in a ventilated dry place, protected from moth.

Radix Pulsatillae

(白头翁, Baitouweng)

Chinese Pulsatilla Root

Chinese Pulsatilla Root is the dried root of *Pulsatilla chinensis* (Bge.) Regel (Fam. Ranuncu-

laceae). The drug is collected in spring and autumn, removed from soil, and dried.

Description Subcylindrical or conical, slightly tortuous, 6–20 cm long, 0.5–2 cm in diameter. Externally yellowish-brown or brown, irregularly and longitudinally wrinkled or furrowed, bark easily exfoliated, the exposed wood yellow, some exhibiting reticulated fissures and cracks, usually with decayed depressed holes near root stock. Root stock slightly swollen, white-tomentose, some showing sheathlike pedicel bases. Texture hard and, fracture yellowish-white or pale yellowish-brown in bark and pale yellow in wood. Odour, slight; taste, slightly bitter and astringent.

Identification (1) Powder: Greyish-brown. Phloem fibres fusiform or spindle-shaped, 100–390 μm long, 16–42 μm in diameter, with lignified walls. Non-glandular hairs unicellular, 13–33 μm in diameter, the base slightly inflated, the walls mostly lignified, some showing spiral or double-spiral striations. Bordered pitted, reticulate and spiral vessels 10–72 μm in diameter.

(2) To 4 g of the powder, add 20 ml of ethanol, heat under reflux for 1 hour, filter. Concentrate the filtrate to about 6 ml on a water bath, cool, add appropriate quantity of acetone, a precipitate is produced. Filter and transfer about 5 mg of the precipitate to a test tube immediately, add 1 ml of acetic anhydride to dissolve, add 1 ml of sulfuric acid along the tube wall, a red to red-violet colour forms at the junction of the two liquids.

Processing Eliminate foreign matter, wash clean, soften thoroughly, cut into thick slices, and dry.

Action To remove toxic heat and relieve bloody dysentery.

Indications Amoebic dysentery; pudendal itching with excessive leukorrhea.

Usage and dosage 9–15 g.

Storage Preserve in a ventilated dry place.

Radix Ranunculi Ternati

(猫爪草, Maozhaocao)

Catclaw Buttercup Root

Catclaw Buttercup Root is the dried root tuber of *Ranunculus ternatus* Thunb. (Fam. Ranunculaceae). The drug is collected in spring and autumn, removed from rootlet and soil, and dried in the sun.

Description Fusiform, mostly fascicled like a cat's claw, 3–10 mm long, 2–3 mm in diameter, apex with yellowish-brown remains of stem and stem scars. Externally yellowish-brown or greyish-yellow, gradually darkening on long storage, with slightly longitudinal wrinkles and some dotted rootlets scars and residual rootlets. Texture compact, fracture whitish or yellowish-white, hollowed or solid, starchy. Odour, slight; taste, slightly sweet.

Identification Transverse section: Epidermal cells tangentially elongated, yellowish-brown, some differentiated into epidermal hairs, slightly lignified. Cortex consisting of 20–30 rows of cells, walls slightly thickened and pitted; endodermis distinct. Stele small, pericycle consisting of 1–2 rows of parenchymatous cells; xylem and phloem, 2 strands each, arranged alternatively. Parenchymatous cells

directly.

Description Ovoid, elliptical or reniform, 6 ~ 8 mm long, 3.5 ~ 5.5 mm in diameter. Externally blackish-purple or greyish-black, shrunken and uneven, with a fruit stalk scar or persistent calyx and a short fruit stalk at the base. Texture light. Epicarp thin, mesocarp relatively lax and soft, easily stripped off, endocarp woody, yellowish-brown, with longitudinal ribs. Seed 1, reniform, purplish-black, oily. Odourless; taste, sweet but slightly bitter and astringent.

Identification To 1 g of the powder add 3 ml of ethanol, shake for 5 minutes, filter, evaporate the filtrate to dryness in a porcelain dish. Dissolve the residue in 1 ml of acetic anhydride, add 1 drop of sulfuric acid; a pink colour is produced, which turns to purple and then to dirty green. Examine under ultra-violet light (365 nm), a yellowish-green fluorescence is observed.

Foreign matter Not more than 3% (Appendix IX A).

Processing *Fructus Ligustri Lucidi* Eliminate foreign matter, wash clean, and dry.

Fructus Ligustri Lucidi (processed with wine) Stew or steam the clean *Fructus Ligustri Lucidi* as described under the method for stewing with wine or steaming with wine (Appendix II D) until the wine is entirely absorbed or steamed thoroughly.

Action To replenish the liver and kidney, improve eyesight and promote the growth of black hair.

Indications Vertigo, tinnitus, weakness in the loins and knees, premature whitening of hair and impaired eyesight due to deficiency of *yin* of the liver and kidney.

Usage and dosage 6 ~ 12 g.

Storage Preserve in a dry place.

Fructus Liquidambaris (路路通, Lulutong)

Beautiful Sweetgum Fruit

Beautiful Sweetgum Fruit is the dried ripe infructescences of *Liquidambar formosana* Hance (Fam. Hamamelidaceae). The drug is collected in winter when the fruit is ripe, removed from foreign matter, and dried.

Description Colletive fruit, composed of numerous small capsules, spheroidal, 2 ~ 3 cm in diameter, with a fruit stalk at the base. Externally greyish-brown or brown, bearing numerous acute spines and small beaked obtuse spines, 0.5 ~ 1 mm long, often broken. Small capsules acrocidial, showing small honeycomb-shaped holes. Texture light and hard, uneasily broken. Odour, slight; taste, weak.

Action To dispel wind and remove obstruction from the collaterals, to cause diuresis, and to stimulate menstrual discharge.

Indications Arthralgia with numbness and muscular contracture; edema; lack of lactation; amenorrhea.

Usage and dosage 5 ~ 9 g.

Storage Preserve in a dry place.

Fructus Litseae

(萼澄茄, Bichengqie)

Mountain Spicy Fruit

Mountain Spicy Fruit is the dried ripe fruit of *Litsea cubeba* (Lour.) Pers. (Fam. Lauraceae). The drug is collected in autumn when ripe, removed from foreign matter, and dried in the sun.

Description Subspheroidal, 4 ~ 6 mm in diameter. Externally brown to blackish-brown, with reticulated wrinkles. Occasionally the base bearing a persistent calyx and a fine fruit stalk. A hard fragile kernel visible when removing the pericarp. Seed 1, cotyledons 2, yellowish-brown, oily. Odour, aromatic; taste, slightly pungent and slightly bitter.

Action To warm the spleen and stomach and promote the flow of *qi* to relieve pain.

Indications Nausea and vomiting due to cold in the stomach, epigastric pain accompanied by feeling of cold; abdominal colic of cold type; turbid urine caused by cold-damp.

Usage and dosage 1.5 ~ 3 g.

Storage Preserve in a cool and dry place.

Fructus Lycii

(枸杞子, Gouqizi)

Barbary Wolfberry Fruit

Barbary Wolfberry Fruit is the dried ripe fruit of *Lycium barbarum* L. (Fam. Solanaceae). The drug is collected in summer and autumn when the fruit turns orange-red. After drying in the shade to make the pericarp shrunken, the drug is exposed to strong sun light until the exocarp is dried and hard, and the pulp soft, removed from the fruit stalk.

Description Subfusiform, slightly flattened, 6 ~ 21 mm long, 3 ~ 10 mm in diameter. Externally scarlet or dark red, marked with a protrudent style scar at the apex, and a white fruit stalk scar at the base. Pericarp pliable and shrunken, sarcocarp fleshy, soft and viscous. Seeds numerous, flat and subreniform, 1.5 ~ 1.9 mm long, 1 ~ 1.7 mm wide, pale yellow or brownish-yellow on surface. Odourless; taste, sweet and slightly sour.

Foreign matter Not more than 1% (Appendix IX A).

Action To benefit the liver and the kidney, to replenish vital essence and to improve eyesight.

Indications General debility with deficiency of vital essence manifested by aching of the loins and knees, dizziness and tinnitus; diabetes caused by internal heat; anemia; impaired vision.

Usage and dosage 6 ~ 12 g.

Storage Preserve in a cool and dry place, protected from heat, moisture and moth.

Anemone raddeana Regel (Fam. Ranunculaceae). The drug is collected in summer, removed from rosette, washed clean, and dried.

Description Long subfusiform, acute and pointed at two ends, slightly curved and one end somewhat expanded. 1–3 cm long, 2–7 mm in diameter. Externally brown to brownish-black, with fine longitudinal wrinkles, the expanded portion usually possessing 1–3 rootlet scars appearing finned-protruding, occasionally with 3–5 indistinct annulations. Texture hard and fragile, easily broken, fracture slightly even, whitish or greyish-brown, almost horny. Odourless; taste, weak and then slightly bitter and pungent.

Identification (1) Transverse section: Epidermis consisting of 1 row of cells, tangentially elongated, outer walls thickened. Cortex of 10 or more rows of subrounded parenchymatous cells. Vascular bundles collateral, 10 or more ones arranged in a ring, phloem cells shrunken, xylem vessels 6–24, cambium ring indistinct. Rays broad, pith relatively large and composed of subrounded parenchymatous cells. Parenchymatous cells filled with starch granules.

Powder: Greyish-brown. Starch granules numerous, simple granules subrounded or elliptical, 2–11 μm in diameter, hilum pointed or shortly cleft-like, striations indistinct; compound granules of 2–4 components. Epidermal cells reddish-brown, yellow or bright yellow, the outer walls suberized and thickened, frequently protruding into the cell to be ridge-like or tubercular. Reticular, spiral or scalariform vessels more frequent, 10–33 μm in diameter, some with bordered pitted vessels.

(2) Warm 2 g of the coarse powder in 10 ml of methanol on a water bath, shake for 10 minutes and filter. To 2 ml of the filtrate add 2 ml of 1% solution of sodium hydroxide and heat on a water bath for 3 minutes. The solution shows a clear bright yellow colour; acidify with 1% hydrochloric acid solution, the bright yellow colour disappears and a turbid milk white colour is produced.

(3) Boil gently 1 g of the coarse powder with 10 ml of 70% ethanol on a water bath for 10 minutes and filter. Evaporate 2 ml of the filtrate to dryness and dissolve the residue in 1 ml of acetic anhydride. Add slowly sulfuric acid along the wall; a purplish colour is produced at the junction of the layers. The upper layer shows a dark green colour on standing.

Action To relieve rheumatic conditions, and to cure carbuncle.

Indications Rheumatoid arthritis with muscular contraction and joint pain; carbuncle with ulceration.

Usage and dosage 1.5–3 g; appropriate quantity for external use.

Storage preserve in a cool and dry place.

Rhizoma Alismatis

✓ (泽泻, Zexie)

Oriental Waterplantain Rhizome

Oriental Waterplantain Rhizome is the dried tuber of *Alisma orientalis* (Sam.) Juzep. (Fam. Alismataceae). The drug is collected in winter when the stem and turn withering, washed clean, dried, and removed from the fibrous root and coarse outer tissue.

Description Subspherical, elliptical or ovate, 2–7 cm long, 2–6 cm in diameter. Externally yellowish-white or yellowish-brown, with irregular transverse-annular shallow furrows and numerous small raised fibrous root scars, occasionally tuberculate bud scars attached to the base. Texture compact, fracture yellowish-white, starchy, with numerous small pores. Odour, slight; taste, slightly bitter.

Identification Powder: Yellowish-brown. Starch granules numerous, simple granules long-ovoid, subspherical or ellipsoid, 3–14 μm in diameter, hilum V-shaped, shortly slit-shaped or Y-shaped; compound granules of 2–3 components. Parenchymatous cells subrounded, with many elliptical pits crowded into pitted areas. Anticlinal walls of endodermis cells sinuous, somewhat relatively thick, lignified, with sparse and minute pit-canals. Oil cavities mostly broken, whole ones subrounded, 54–110 μm in diameter, sometimes oil drops contained in secretory cells visible.

Total ash Not more than 5% (Appendix X K).

Acid-insoluble ash Not more than 5.0% (Appendix X K).

Processing *Rhizoma Alismatis* Eliminate foreign matter, soak briefly, soften thoroughly, cut into thick slices, and dry.

Rhizoma Alismatis (Processed with salt) Stir-fry the slices of *Rhizoma Alismatis* as described under the method for stir-frying with salt-water (Appendix II D) to dryness.

Action To cause diuresis, and to remove damp-heat.

Indications Edema with oliguria; diarrhea with diminished discharge of urine; vertigo due to retention of fluid; acute urinary infection with difficult painful urination; hyperlipemia.

Usage and dosage 6–9 g.

Storage Preserve in a dry place, protected from moth.

Rhizoma Alpiniae Officinarum

(高良姜, Gaoliangjiang)

Lesser Galangal Rhizome

Lesser Galangal Rhizome is the dried rhizome of *Alpinia officinarum* Hance (Fam. Zingiberaceae). The drug is collected at the end of summer and the beginning of autumn, removed from fibrous root and remaining leaf scales, washed clean, cut into sections, and dried in the sun.

Description Cylindrical, often curved and branched, 5–9 cm long, 1–1.5 cm in diameter. Externally brownish-red to dark brown, with fine, numerous longitudinal wrinkles and grayish-brown sinuous, annular nodes, each node 0.2–1 cm long, bearing round root scars at the lower part. Texture hard and tenacious, uneasily broken, fracture greyish-brown or reddish-brown, fibrous. Stele occupying about 1/3 area of the rhizome. Odour, aromatic; taste, pungent.

Identification Transverse section: The outer walls of epidermal cells thickened, some cells containing reddish-brown non-crystalline masses. Vascular bundles of leaf trace relatively abundant in cortex, collateral. Endodermis distinct. Collateral vascular bundle numerous in stele, vascular bundle sheath fibres arranged in a ring and lignified. Secretory cells abundantly scattered in parenchyma of cortex and stele, containing yellow or reddish-brown resinous con-

And after steaming the drug is partially dried in the sun, cut into thick slices and dried thoroughly. "shougoujipian".

Description Irregularly long lump-shaped, 10–30 cm long, 2–20 cm in diameter. Externally dark brown, with remains of golden hairs; upper part exhibiting several reddish-brown woody petioles and the lower part showing remains of black fibrous roots. Texture hard, uneasily broken. Odourless; taste, weak and slight astringent.

Shengoujipian Irregularly long lump-shaped or rounded, 5–20 cm long, 2–10 cm in diameter, 1.5–5 mm thick, transverse cut surface pale brown, relatively smooth, exhibiting a brownish-yellow raised ring or stripe of xylem at a distance of 1–4 mm from edges. Edges irregular, with remains of golden hairs occasionally; texture fragile, easily broken, starchy.

Shougoujipian Blackish-brown, texture hard.

Identification Transverse section: Epidermis consisting of 1 layer of cells, with remains of golden nonglandular hairs. The inner of epidermis exhibiting 10 or over rows of brownish yellow sclerenchymatous cells, pits distinct. Xylem arranged in rings, composed of the tracheids, both the inner and outer parts exhibiting phloem and endodermis. Cortex and pith composed of parenchymatous cells, filling with starch granules, some with yellowish brown contents.

Processing *Rhizoma Cibotii* Eliminate foreign matter; for the drug not sliced, wash clean, soften thoroughly, cut into thick slices, and dry.

Rhizoma Cibotii (scalding) Scald the slices of *Rhizoma Cibotii* with sand as described under the method for scalding (Appendix II D) until inflated, and after cooling remove the remainder of hairs.

Action To replenish the liver and the kidney, to strengthen the back, and to relieve rheumatic conditions.

Indications Weakness and aching of the back and loins, limpness of the legs, rheumatic arthralgia.

Usage and dosage 6–12 g.

Storage Preserve in a ventilated and dry place, protected from moisture.

Rhizoma Cimicifugae

(升麻, Shengma)

Largetrifoliosus Bugbane Rhizome

Largetrifoliosus Bugbane Rhizome is the dried rhizome of *Cimicifuga heracleifolia* Kom., *Cimicifuga dahurica* (Turcz.) Maxim. or *Cimicifuga foetida* L. (Fam. Ranunculaceae). The drug is collected in autumn, removed from soil and fibrous root, and then dried in the sun.

Description Irregular long pieces, frequently branched, nodular, 10–20 cm long, 2–4 cm in diameter. Externally blackish-brown or brown, rough, with remains of many wiry fibrous roots, the upper part showing several round and hollow remains of stems, the inner walls with reticulate furrows, and the lower part lumpy, with fibrous root scars. Texture light and hard, uneasily broken, fracture uneven, cracked, fibrous, yellowish-green or yellowish-white. Odour, slight; taste, slightly bitter and astringent.

Total ash Not more than 8.0% (Appendix IX K).

Processing Eliminate foreign matter, soak briefly, wash clean, soften thoroughly, cut into thick slices, and dry.

Action To induce perspiration and promote eruption, to remove toxic heat, and to cure drooping and ptosis.

Indications Headache caused by wind-heat toothache, ulcers in the mouth, sore throat; measles with inadequate eruption and other eruptive febrile diseases; prolapse of the rectum or the uterus.

Usage and dosage 3–9 g.

Storage preserve in a ventilated and dry place.

Rhizoma Coptidis ✓ (黄连, Huanglian)

Golden Thread

Golden Thread is the dried rhizome of *Coptis chinensis* Franch., *Coptis deltoidea* C. Y. Cheng et Hsiao or *Coptis teeta* Wall. (Fam. Ranunculaceae), commonly known as "Wei-lian", "Yalian" or "Yun-lian", respectively. The drug is collected in autumn, removed from rootlet and soil, and dried.

Description *Rhizome of Coptis chinensis* Frequently gathered to a cluster, curved, like "chicken's feet", single rhizome 3–6 cm long, 3–8 mm in diameter. Externally greyish-yellow or yellowish-brown, rough, bearing irregular nodular protrusions, rootlets and remains of rootlets, some internodes smooth as stem. The upper part mostly remained with brown scale leaves, apex often bearing remains of stems or petioles. Texture hard, fracture uneven, bark orange-red or dark brown, wood brightly yellow or orange-yellow, radially arranged, pith sometimes hollowed. Odour, slight; taste, very bitter.

Rhizome of Coptis deltoidea Frequently single, somewhat cylindrical, slightly curved, 4–8 cm long, 0.5–1 cm in diameter. Internodes smooth and relatively long. Apex with some remains of stems.

Rhizome of Coptis teeta Curved hook-like, frequently single, relatively small.

Identification (1) Transverse section:

Rhizome of Coptis chinensis Cork cells several layers. Cortex broader, stone cells singly scattered or grouped. Pericycle fibres in bundles or accompanied with a few stone cells, both yellow. Collateral vascular bundles arranged in ring. Interfascicular cambium indistinct. Xylem yellow, lignified, xylem fibres well developed. Pith consisting of parenchymatous cells, stone cells absent.

Rhizome of Coptis deltoidea Pith with stone cells.

Rhizome of Coptis teeta In cortex, pericycle and pith, stone cells absent.

(2) To 1 g of the coarse powder, add 10 ml of ethanol, heat to boil, allow to cool, and filter. To 5 drops of the filtrate, add 1 ml of diluted hydrochloric acid TS and a small quantity of chlorinated lime. A red colour is produced; to another 5 drops of the filtrate add 2–3 drops of 5% solution of gallic acid in ethanol, evaporate to dryness, add several drops of sulfuric acid to the residue while hot; a dark green colour is produced.

(3) To 50 mg of the powder, add 5 ml of methanol, heat

under reflux on a water bath for 15 minutes, filter, add methanol to 5 ml as the test solution. Prepare a solution of Rhizoma Coptidis reference drug in the same manner as the reference drug solution. Dissolve berberine hydrochloride CRS in methanol to produce a solution containing 0.5 mg per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B), using silica gel G as the coating substance and benzene-ethyl acetate-isopropanol-water (6:3:1.5:1.5:0.3) as the mobile phase. Apply separately to the plate 1 μ l each of the three solutions. After developing in a chamber pre-saturated with the vapour of concentrated ammonia TS for 15 minutes and removal of the plate, dry it in air and examine under ultraviolet light (365 nm). The yellow fluorescent spots in the chromatogram obtained with the test solution correspond in position and colour to the spots in the chromatogram obtained with the reference drug solution; and a yellow fluorescent spot due to berberine corresponds to the spot in the chromatogram obtained with the reference solution.

Total ash Not more than 5.0% (Appendix IX K).

Assay Weigh accurately 0.1 g of the powder in a 100 ml of volumetric flask, add 95 ml hydrochloric acid-methanol (1:100), heat at 60°C on a water bath for 15 minutes, ultrasonicate for 30 minutes, allow to stand overnight, dilute with methanol to volume, mix well, filter, use the filtrate as the test solution. Dissolve berberine hydrochloride CRS, weighed accurately, in methanol to produce a solution containing 0.04 mg per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B), using silica gel G as the coating substance and benzene-ethyl acetate-isopropanol-water (6:3:1.5:1.5:0.3) as the mobile phase. Apply 1 μ l of the test solution and 1 μ l, 3 μ l of the reference solution alternatively to the plate. After developing 8 cm in a chamber pre-saturated with the vapour of concentrated ammonia TS for 15 minutes and removal of the plate, dry it in air. Carry out the method for thin layer chromatography (thin layer chromatographic scanning method) (Appendix VI B), scan with fluorescence mode at the wavelength of $\lambda_{ex} = 366\text{nm}$, measure the integration value of the fluorescent strength, and calculate.

It contains not less than 3.6% of berberine, calculated as berberine hydrochloride ($\text{C}_{20}\text{H}_{18}\text{ClNO}_4$).

Processing *Rhizoma Coptidis* Eliminate foreign matter, soften thoroughly, cut into thin slices, dry it in air, or break to pieces before use.

Rhizoma Coptidis (processed with wine) Stir-fry the clean Rhizoma Coptidis as described under the method for stir-frying with wine (Appendix II D) to dryness, using 12.5 kg of yellow rice wine per 100 kg of Rhizoma Coptidis.

Rhizoma Coptidis (processed with ginger) Stir-fry the clean Rhizoma Coptidis as described under the method for stir-frying with ginger juice (Appendix II D) to dryness, using 12.5 kg of ginger per 100 kg of Rhizoma Coptidis.

Rhizoma Coptidis (Processed with Fructus Evodiae) Decoct Fructus Evodiae with a quantity of water, mix the decoction with clean Rhizoma Coptidis, until the decoction is exhausted, then stir-fry to dryness.

To each 100 kg of Rhizoma Coptidis add 10 kg of Fructus Evodiae.

Carry out the method for determination of total ash as described above, for all of these processed products, not more than 4.0%.

Action To remove damp-heat, quench fire and counteract toxicity.

Rhizoma Coptidis (processed with wine) To remove fire from the upper part of the body.

Rhizoma Coptidis (processed with ginger) To remove fire from the stomach, regulate the stomach function and relieve vomiting.

Rhizoma Coptidis (processed with Fructus Evodiae) To soothe the liver, regulate the stomach function and relieve vomiting.

Indications Attack of damp-heat manifested by stuffiness and fullness sensation in the abdomen, or causing acute dysentery of jaundice; high fever accompanied by impairment of consciousness; fidgetiness and insomnia due to exuberant fire; spitting of blood and epistaxis caused by heat in the blood; inflammation of the eye; acid regurgitation; toothache; diabetes; carbuncles and sores; external use for eczema and other skin diseases with exudation; purulent discharge from the ear.

Rhizoma Coptidis (processed with wine) Inflammation of the eye; ulcers in the mouth.

Rhizoma Coptidis (processed with ginger) Stuffiness and fullness sensation in the abdomen with nausea and vomiting caused by damp-heat in combination with cold.

Rhizoma Coptidis (processed with Fructus Evodia) Nausea, vomiting and acid regurgitation in disharmony of the liver and the stomach.

Usage and dosage 2~5 g; appropriate quantity for external use.

Storage Preserve in a ventilated and dry place.

Rhizoma Corydalis

(延胡索, Yanhusuo)

Yanhusuo

Yanhusuo is the dried tuber of *Corydalis turtchaninovii* Bess. (Fam. Papaveraceae). The drug is collected in early summer when the plant is withered, removed from fibrous root, washed clean, boiled in water until the centre of the cut surface is just devoid of white core, and dried in the sun.

Description Irregularly oblate 0.5~1.5 cm in diameter. Externally yellow or yellowish-brown, irregularly reticulate-wrinkled. Apex with slight dented stem scar, base usually tuberculate. Texture hard and fragile, fracture yellow, horny, waxy-shiny. Odour, slight; taste, bitter.

Identification (1) Powder: Greenish-yellow. Gelatinised masses of starch granules pale yellow or nearly colourless. Sclenchyma in hypodermis greenish-yellow, cells polygonal, subsquare or elongated, walls slightly sinuous lignified, some beaded, finely pitted. Stone cells pale yellow, subrounded or oblong, up to 60 μ m in diameter, walls relatively thickened, finely pitted. Spiral vessels 16~32 μ m in diameter.

(2) Macerate 2 g of the powder in 20 ml of sulfuric acid solution (0.25 mol/L) for a while and filter. To 2 ml of the filtrate add 0.3 ml of a mixture of 0.4 ml of 1% ferric chloride solution and 1% potassium ferricyanide solution: a deep green colour is produced which gradually becomes a deep blue colour, and a deep blue precipitate is produced on standing. To another 2 ml of the filtrate add 1 drop of potassium dichromate TS: a yellow precipitate is produced.

(3) To 1 g of the powder add 50 ml of methanol, ultrasonicate for 30 minutes, filter and evaporate the filtrate to dry-

5–20 cm long, 2–6 cm wide, upper surface dark greyish-green, sometimes small deeper coloured prominences being visible; apex obtuse, margins entire or slightly undulate, base attenuate and decurrent into the petiole appearing wing-shaped; petioles 4–10 cm long, pale brownish-yellow. Texture fragile. Odour, slight; taste, slightly sour, bitter and astringent.

Identification (1) Powder: Greenish-brown. Anticlinal walls of lower epidermal cells slightly sinuous and somewhat beaded; stomata anomocytic, with 3–4 subsidiary cells. Transverse section of mesophyll indistinctly differentiated into palisade tissue and spongy tissue.

(2) To 0.5 g of the powder add 20 ml of chloroform, heat under reflux on a water bath for 1 hour, filter and evaporate the filtrate to 1 ml as the test solution. Dissolve indigotin CRS and indirubin CRS in chloroform to produce a solution containing 1 mg of each per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B), using silica gel G as the coating substance and benzene-chloroform-acetone (5:4:1) as mobile phase. Apply separately to the plate 5 μ l of the two solutions. After developing and removal of the plate, dry it in air. The blue spot and pale purplish-red spot due to indigotin and indirubin in the chromatogram obtained with the test solution correspond in position and colour to the spots in the chromatogram obtained with the reference solution.

Processing Eliminate foreign matter, wash rapidly, cut into pieces and dry.

Action To remove toxic heat, reduce heat in blood, and promote subsidence of eruptions.

Indications High fever with impairment of consciousness and skin eruptions in epidemic diseases; jaundice; acute dysentery; mumps; inflammation of the throat, erysipelas, carbuncle.

Usage and dosage 9–15 g.

Storage Preserve in a ventilated dry place, protected from mould.

✓ Folium Mori (桑叶, Sangye)

Mulberry Leaf

Mulberry Leaf is the dried leaf of *Morus alba* L. (Fam. Moraceae). The drug is collected at the early frost season, removed from foreign matter and dried in the sun.

Description Mostly crumpled and broken. When whole, petioled, ovate or broadly ovate, 8–15 cm long, 7–13 cm wide; apex acuminate, base truncate, round or cordate, margins dentate or obtuse-dentate, some irregularly partite. Upper surface yellowish-green or pale yellowish-brown, some with small warty protrusions; lower surface relatively light in colour, veins prominent, lateral veins reticulated, sparsely pubescent on the veins, cluster of hairs occurring at the base. Texture fragile. Odour, slight; taste, weak, slightly bitter and astringent.

Identification Powder: Yellowish-green or yellowish-brown. The upper epidermis having large crystal cells, containing cystolith, 47–77 μ m in diameter. Stomata anomocytic in lower epidermis, with 4–6 subsidiary cells. Nonglandular hairs unicellular, 50–230 μ m long. Clusters of calcium oxalate 5–16 μ m in diameter; prisms occasionally

visible.

Processing Eliminate foreign matter, rub to break, remove the petioles, sift off the dust.

Action To dispel wind-heat and to remove heat from the lung, to subdue hyperactivity of the liver and improve eyesight.

Indications Upper respiratory infection, heat in the lung with dry cough; dizziness, headache, inflammation of the eye, blurred vision.

Usage and dosage 5–9 g.

Storage Preserve in a dry place.

✓ Folium Nelumbinis (荷叶, Heye)

Lotus Leaf

Lotus Leaf is the dried leaf of *Nelumbo nucifera* Gaertn. (Fam. Nymphaeaceae). The drug is collected in summer and autumn, dried in the sun to remove most of water, removed from the petioles, folded to semi-rounded or plicate, and dried again.

Description Semi-rounded or fan-shaped, subrounded, when spread, 20–50 cm in diameter, margins entire or slightly sinuous. Upper surface dark green or yellowish-green, relatively rough, lower surface pale greyish-brown, relatively smooth, with 21–22 thick veins, radiating from the centre to the border, with convex remains of petiole in the centre. Texture fragile, easily broken. Odour, slightly aromatic; taste, slightly bitter.

Identification Powder: Greyish-green. Upper epidermal cells polygonal, with papilla or short tomentose convexes; stomata, anomocytic, subsidiary cells 5–8. Anticlinal walls of lower epidermal cells slightly sinuous, sometimes beaded. Clusters of calcium oxalate numerous up to 40 μ m in diameter.

Processing *Folium Nelumbinis* Spray with water, moisten briefly, cut into slivers and dry.

Folium Nelumbinis (carbonized) Carbonize the clean *Folium Nelumbinis* as described under the method for carbonizing by calcining (Appendix II D).

Action To relieve summer-heat, to invigorate the spleen function of the spleen and arrest bleeding by reducing heat in blood.

Folium Nelumbinis (carbonized): To arrest bleeding, remove blood stasis.

Indications Summer-heat with dire thirst; diarrhea caused by summer-damp or hypofunction of the spleen; spitting of blood, epistaxis, hematochezia and abnormal uterine bleeding caused by heat in blood.

Folium Nelumbinis (carbonized): Various kind of bleeding and massive postpartum hemorrhage.

Usage and dosage 3–9 g: fresh *Folium Nelumbinis*: 15–30 g.

Folium Nelumbinis (carbonized): 3–6 g.

Storage Preserve in a ventilated dry place, protected from moth.

monia TS, then macerate 10 ml of chloroform for 30 minutes and ultrasonicate for 30 minutes, filter. Evaporate the filtrate to dryness, dissolve the residue in 1 ml methanol. Take 3~4 drops of the methanol solution into a 10 ml stoppered test tube. Add 0.5 ml of chromotropic acid and 3 ml of sulfuric acid and heat the test tube on a water bath for 10 minutes, a deep purple colour appears.

(3) Add 15 ml of ethanol to 1 g of the reference drug of Radix Zanthoxyli, warm macerate for 30 minutes then ultrasonicate for 30 minutes, filter. Evaporate the filtrate to dryness, dissolve the residue in 1 ml of ethanol and use it as the reference drug solution. Carry out the method for thin layer chromatography (Appendix VI B) using silica gel G as the coating substance and benzene-ethyl acetate-methanol-isopropanol-concentrated ammonia TS (20:5:3:1:0.12) as the mobile phase. Apply separately to the plate 2 μ l of each of the test solution, the reference drug solution, and the reference solution used for assay. After developing in a chamber pre-equilibrated with mobile phase for 10 minutes and removal of the plate, dry it in air and examine under ultraviolet light (365 nm). A fluorescent spot in the chromatogram obtained from the test solution corresponds in colour and position to the spot in the chromatogram obtained from the solution of reference drug, and a light yellow fluorescent spot corresponds in colour and position to the spot in the chromatogram obtained from the reference solution used for assay.

(4) Dissolve ethoxychelerythrine CRS in methanol to produce a solution containing 1 mg per ml used as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B) using silica gel G as the coating substance and toluene-ethyl acetate-methanol (25:2:0.1) as the mobile phase. Apply separately to the plate 2 μ l of the reference solution, 2 μ l of each of the solution of reference drug and test solution used in identification (3). After developing in a chamber pre-equilibrated with mobile phase for 10 minutes and removal of the plate, dry it in air, examine under ultra-violet light. A fluorescent spot in the chromatogram obtained from the test solution corresponds in colour and position to the spot in the chromatogram obtained from the reference drug, and orange-yellow fluorescent spot corresponds in colour and position to the spot in the chromatogram obtained from reference solution.

Assay To 1 g coarse powder, weighed accurately, in a Soxhlet's extractor, extract by heating under reflux until the reflux fluid becomes colourless. Concentrate the extract on a water bath to about 2 ml, transfer it into a 10 ml volumetric flask, add methanol to volume, mix well and use it as the test solution. Dissolve nitidine chloride CRS, weighed accurately, in methanol to produce a solution containing 0.5 mg per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B) using silica gel G containing sodium carboxymethyl cellulose as the coating substance and, weighed accurately, benzene-ethyl acetate-methanol-isopropanol-concentrated ammonia TS (20:5:3:1:0.12) as the mobile phase. Apply alternatively 4 μ l of test solution, 1 μ l and 4 μ l of reference solution to the plate. After developing and removal of the plate, dry it in air, examine under ultra-violet light (365 nm), carry out the thin layer chromatography (thin layer chromatographic scanning method) (Appendix VI B), scan the chromatogram at wavelength of $\lambda_s = 300$ nm, measure the integration values of absorbance for test solution and reference solution, calculate. It contains not less than 0.25% of nitidine chloride ($C_{21}H_{18}NO_2$), calculated on the dried basis.

Action To promote the flow of qi, relieve pain, to eliminate blood stasis, to promote blood circulation and dispel wind.

Indications Traumatic injury, rheumatic arthralgia, stomach-ache, teeth-ache, bitten by venomous snake, applied for burn caused by hot liquid or fire.

Usage and dosage 5~10 g; appropriate quantity for external use. Abrasive powder for application or simmer in water for washing the affected part of body.

Precaution Overdose is avoided, incompatible with food of sour flavour.

Storage Preserve in a dry place, protected from moisture and moth.

Ramulus Cinnamomi ✓ (桂枝, Guizhi)

Cassia Twig

Cassia Twig is the dried young stem of *Cinnamomum cassia* Presl (Fam. Lauraceae). The drug is collected in spring and summer, removed from leaf, dried in the sun or dried in the sun after sliced.

Description Long cylindrical, much-branched, 30~75 cm long, the thick end 0.3~1 cm in diameter. Externally brown to reddish-brown, with longitudinal lines, fine wrinkles, dotted leaf-scars, branch-scars and bud-scars, lenticels dotted or dotted elliptic. Texture hard and fragile, easily broken. Slices 2~4 mm thick, cut surface showing reddish-brown in bark, yellowish-white to pale yellowish-brown in wood, pith subsquare. Odour characteristic aromatic; taste, sweet and slightly pungent, relatively strong in bark.

Identification (1) Transverse section: Epidermis consisting of 1 layer of cells, non-glandular hairs unicellular, visible in young branches. Cork consisting of 3~5 layers of cells, the inner cells with thickened outer walls. Oil cells and stone cells scattered in cortex. Stone cells groups in pericycle interruptedly arranged in a ring, accompanied by fibre bundles. Secretory cells and fibres scattered in phloem. Cambium distinct. Xylem rays 1~2 cells wide, containing brown contents; vessels scattered singly or 2 to several aggregated; wood fibres with relatively thin walls, and differentiated uneasily from wood parenchymatous cells. In pith the walls of cells slightly thickened and lignified. Cells of rays containing fine needle crystals of calcium oxalate. (2) To 0.5 g of the powder add 10 ml of ethanol, stopped tightly, macerate for 20 minutes with constant shaking, and filter, use the filtrate as the test solution. Dissolve cinnamic aldehyde CRS in ethanol to produce a solution containing 1 μ l per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B), using silica gel G as the coating substance and petroleum ether (boiling range 60~90°C)-ethyl acetate (85:15) as the mobile phase. Apply separately to the plate 10~15 μ l of the test solution and 2 μ l of the reference solution. After developing and removal of the plate, dry it in air, and spray with 0.1% 2,4-dinitrophenyl-hydrazine solution. The orange-red spot in the chromatogram obtained with the test solution corresponds in position and colour to the spot in the chromatogram obtained with the reference solution.

Processing Eliminate foreign matter, soak briefly, wash clean, soften thoroughly, cut into thin slices, and dry in air.

Slices subrounded, elliptic or sections irregular, externally some with dotted lenticels and longitudinal lines, bark red-

dish brown, wood yellowish-white or pale yellowish-brown, pith subrounded or slightly square.

Action To induce perspiration, to warm the *channels* and stimulate menstrual discharge, to reinforce *yang*, to relieve palpitation, and to promote the descending of *qi*.

Indications Common cold; epigastric pain with cold feeling; amenorrhea due to *cold* in blood; arthralgia; edema; cardiac palpitation; gastro-intestinal-neurosis with a feeling of masses of gas rushing up through the chest to the throat from the lower abdomen.

Usage and dosage 3-9 g.

Storage Preserve in a cool and dry place.

Ramulus et Folium Picrasmae

(苦木, Kumu)

Indian Quassia-wood

Indian Quassia-wood is the dried stem and leaf of *Picrasma quassioides* (D. Don) Benn. (Fam. Simarubaceae). The drug is collected in summer and autumn, and dried.

Description Stems Cylindrical, varying in length, 0.5-2cm in diameter; externally greyish-green or brownish-green, with fine and dense longitudinal striations and numerous dotted lenticels; texture fragile, easily broken, fracture uneven, pale yellow, the young branches pale-coloured and large medullated, compound, leaves odd-pinnate easily falling off; leaflets ovate-elongated elliptical or ovate-lanceolate, subsessile, 4-16 cm long, 1.5-6 cm wide, apex acute, base oblique or slightly rounded, margins crenate, both surfaces usually green, sometimes the lower surface pale purplish-red, pubescent along the midrib. Odour, slight; taste, extremely bitter.

Identification (1) Powder: Yellowish-green. Upper epidermal cells of the leaf polygonal; stomata anomocytic, usually visible on the lower epidermal. Mesophyll cells frequently containing clusters of calcium oxalate, fibre bundles surrounded by parenchymatous cells containing clusters or prisms of calcium oxalate, forming crystal fibres.

(2) Macerate 1 g of the powder in 10 ml methanol over night, filter, evaporate the filtrate to dryness, dissolve the residue in 10 ml of methanol and use it as the test solution. Prepare a solution of Ramulus et Folium Picrasmae reference drug in the same manner as the reference drug solution. Carry out the method for thin layer chromatography (Appendix VI B) using silica gel G containing sodium carboxymethyl cellulose as the coating substance and a mixture of chloroform-methanol (85:15) as the mobile phase. Apply separately 10 μ l of each of the above two solutions to the plate. After developing and removal of the plate, dry it in air, spray with modified potassium iodobismuthate TS. A spot in the chromatogram obtained from the test solution corresponds in colour and position to the spot in the chromatogram obtained from the reference drug solution.

Processing Eliminate foreign matter, wash the stems clean, soften thoroughly, cut into slices, and dry in the sun; spray the leaves with clean water, moisten briefly, cut into slivers, and dry in the sun.

Action To act against bacteria, and relieve inflammation, to remove *damp*, and to counteract toxicity.

Indications Colds, acute tonsillitis, pharyngitis, colitis, bacillary dysentery, eczema, boils, venomous snake bite.

Usage and dosage 3-4.5 g of its branches or 1-3 g of its leaves; appropriate quantity for external use.

Storage Preserve in a dry place.

Ramulus Mori

(桑枝, Sangzhi)

Mulberry Twig

Mulberry Twig is the dried young branch of *Morus alba* L. (Fam. Moraceae). The drug is collected at the end of spring and the beginning of summer, removed from leaf, and dried in the sun, or cut into slice while fresh, and dried in the sun.

Description Long cylindrical, branched occasionally, varying in length, 0.5-1.5 cm in diameter. Externally greyish-yellow or yellowish-brown, with numerous yellowish-brown dotted lenticels and fine longitudinal striations, and with greyish-white slightly semiorbicular leaf scars and yellowish-brown axillary buds. Texture hard and tenacious, uneasily broken, fracture fibrous. Slices 0.2-0.5 cm thick, bark slightly thin, wood yellowish-white, medullary rays radiate, pith white or yellowish-white. Odour, slight; taste, weak.

Identification Powder: Pale greyish-yellow. Fibres numerous, scattered singly or in bundles, pale yellow or colourless, slightly sinuous, 10-30 μ m in diameter, walls thickened, 5-15 μ m, pit-canals indistinct, lumina small. Stone cells pale yellow, subrounded or subsquare, 15-40 μ m in diameter, walls thickened, 5-20 μ m, lumina small. Sclerenchymatous cells grouped or scattered singly, similar to the stone cell in the shape and size, lumina containing 1-2 prisms of calcium oxalate, square, rhombic, polyhedral or biconelike, 5-20 μ m in diameter.

Extractives Carry out the hot extraction method as described under the determination of ethanol-soluble extractives (Appendix X A), using ethanol as the solvent, not less than 3.0%.

Processing *Ramulus Mori* Wash the whole ones clean and soften thoroughly, cut into thick slices, and dry in the sun.

Ramulus Mori (Stir-fried) Stir-fry the slices of *Ramulus Mori* as described under the method for simple stir-frying (Appendix II D) to a yellowish colour.

Action To relieve rheumatic arthralgia.

Indications Aching and numbness of joints, particularly of the shoulders and arms.

Usage and dosage 9-15 g.

Storage Preserve in a dry place.

Ramulus Uncariae cum Uncis

(钩藤, Gouteng)

Gambir Plant

Gambir Plant is the dried hook-bearing stem branch of *Uncaria rhynchophylla* (Miq.) Jacks., *Uncaria macrophylla* Wall., *Uncaria hirsuta*

distinct. Parenchymatous cells containing minute needles of calcium oxalate.

Jianlongdan The tissues outside the endodermis mostly falling off. Vessels in xylem well developed and evenly and densely distributed. Pith absent.

Power Yellowish-brown.

Longdan Cells of exodermis spindle-shaped in surface view, each cell divided by transverse walls into several small rectangular cells. Cells of endodermis subrectangular in surface view, fairly large, periclinal walls showing minute transverse striations, each cell divided by longitudinal septa walls into several small palisade-like cells, mostly longitudinal septa beaded. Parenchymatous cells containing minute needle crystals of calcium oxalate. Reticulate and scalariform vessels up to about 45 μm in diameter.

Jianlongdan Exodermis absent. Cells of endodermis sub-square or subrectangular, transverse striations of the periclinal walls relatively thick and dense, some up to 3 μm thick, each cell divided into several small palisade-like cells, septa slightly thickened or beaded.

(2) Macerate 0.5 g of the powder in 5 ml of methanol for 4–5 hours, filter, concentrate the filtrate to about 2 ml and use it as the test solution. Dissolve gentiopicoside CRS in methanol to produce a solution containing 2 mg per ml used as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B), using silica gel GF₂₅₄ as the coating substance and ethyl acetate-methanol-water (20:2:1) as the mobile phase. Apply separately 5 μl of each of the above two solutions to the plate, develop twice in the mobile phase. After developing and removal of the plate, dry it in air, examine under ultra-violet light (254 nm). A spot in the chromatogram obtained with the test solution corresponds in position and colour to the spot in the chromatogram obtained with the reference solution.

Total ash Not more than 7% (Appendix X K).

Processing Eliminate foreign matter, wash clean, soften thoroughly, cut into sections, and dry.

Action To eliminate *damp-heat* and quench the *fire* of the liver and gall bladder.

Indications Jaundice caused by *damp-heat*; swelling and itching of the vulva with excessive leukorrhea; prolonged erection of the penis with spontaneous emission; eczema accompanied by itching; blood-shot eyes, impairment of hearing, pain in the costal regions and bitter taste in the mouth; convulsion.

Usage and dosage 3–6 g.

Storage Preserve in a dry place.

Radix Gentianae Macrophyllae

(秦艽, Qinjiao)

Largeleaf Gentian Root

Largeleaf Gentian Root is the dried root of *Gentiana macrophylla* Pall., *Gentiana straminea* Maxim., *Gentiana crassicaulis* Duthie ex Burk. or *Gentiana dahurica* Fisch. (Fam. Gentianaceae). According to the description the former three species are known as "Qinjiao" and "Mahujiao", respectively. The latter is known as "Xiaoqinjiao". The drug is collected in spring and

autumn, removed from soil; "Qinjiao" and "Mahujiao" are softened in the sun, either piled up until the drug becomes reddish-yellow or greyish-yellow on the surface, spread out and dried in the sun, or dried in the sun directly after collecting; as for "Xiaoqinjiao", the black bark is rubbed off while fresh and dried in the sun.

Description *Qinjiao* Subcylindrical, the upper part thick and the lower part thin, twisted, 10–30 cm long, 1–3 cm in diameter. Externally yellowish-brown or greyish-yellow, with longitudinal or twisted wrinkles. Remains of stem bases and fibrous pericladium occurring at the apex. Texture hard and fragile, easily broken, fracture soft, bark yellow or brownish-yellow, wood yellow. Odour, characteristic; taste, bitter and slightly astringent.

Mahujiao Subconical, frequently expanded by some small roots gathered, up to 7 cm in diameter. Externally dark brown, rough, with fissures, showing reticulated pits. Texture lax and fragile, easily broken, fracture frequently rotten-wood-shaped.

Xiaoqinjiao Subconical or subcylindrical, 8–15 cm long, 0.2–1 cm in diameter. Externally brownish-yellow. Main root frequently 1, having fibrous pericladia on the remains of stem bases, often branched at the lower part. Fracture yellowish-white.

Identification (1) Macerate 2 g of the coarse powder in 30 ml of chloroform-methanol-concentrated ammonia TS (75:25:5) for 2 hours and filter. Concentrate the filtrate on a water bath to about 1 ml, add 2 ml of hydrochloric acid solution (1 mol/L) and continue to evaporate the chloroform, cool and filter. Transfer the filtrate to two test tubes, to one tube add mercuric potassium iodide TS, a pale yellowish-white precipitate is produced; to another tube add potassium iodobismuthate TS, a brownish-red precipitate is produced.

(2) Examine the fracture under an ultra-violet light (365 nm), a yellowish-white or golden yellow fluorescence is shown.

Extractives Carry out the hot maceration method as described under the determination of ethanol-soluble extractives (Appendix X A), using ethanol as the solvent, not less than 24.0%.

Processing Eliminate foreign matter, wash clean, soften thoroughly, cut into thick slices, and dried in the sun.

Action To relieve rheumatic conditions, and to remove *damp-heat*.

Indications Rheumatic or rheumatoid arthritis with muscular contracture and severe joint pain; fever recurring daily in the afternoon, fever in infants with malnutrition.

Usage and dosage 3–9 g.

Storage Preserve in a ventilated and dry place.

Radix Ginseng

(人參, Renshen)

Ginseng

Ginseng is the dried root of *Panax ginseng* C. A. Mey. (Fam. Araliaceae). The drug derived from the cultivated form is known as "Yuanshen" (Garden Ginseng) and the drug derived from the

wild origin is known as "Shanshen" (Wild Ginseng). The drug is collected in autumn and washed clean. Sun-dried or bake-dried Yuanshen is known as "Shengshaishen" (Sun-dried Ginseng). Sun-dried Shanshen is known as "Shengshaishanshen" (Sun-dried Wild Ginseng).

Description Sun-dried Ginseng Main roots fusiform or cylindrical, 3–15 cm long, 1–2 cm in diameter; externally greyish-yellow, upper part or entire root exhibiting sparse, shallow, interrupted and coarse transverse-striations and distinct longitudinal wrinkles; lower part bearing 2–3 branch roots and numerous slender rootlets with inconspicuous minute tubercles. Rhizomes (Lutou) 1–4 cm long, 0.3–1.5 cm in diameter, mostly constricted and curved, bearing adventitious roots (Ding) and showing sparse depressed-circular stem scars (Luan). Texture relatively hard, fracture yellowish-white, starchy, cambium ring brownish-yellow, bark exhibiting yellow-brown dotted resin canals and radial clefts. Odour, characteristic; taste, slightly bitter and sweet.

Sun-dried Wild Ginseng Main roots as long as or shorter than rhizome, V-shaped, rhomboid or cylindrical, 2–10 cm long; externally greyish-yellow, longitudinally wrinkled, upper end with dense deep depressed annulations, branch roots mostly 2, rootlets slender, orderly arranged and showing some distinct warts, known as "pearl-like knot" (Zhenzhugeda). Rhizomes slender, the upper part exhibiting dense stem scars, adventitious roots relatively thick, like a kernel of Chinese date.

Identification (1) Transverse section: Cork consisting of several rows of cells. Cortex narrow. Phloem showing clefts in the outer part, and parenchymatous cells densely arranged and scattered with resin canals containing yellow secretions in the inner part. Cambium in a ring. Xylem rays broad, vessels singly scattered, or grouped, interruptedly arranged radially, occasionally accompanied by non-lignified fibres. Parenchymatous cells containing clusters of calcium oxalate.

Powder of Sun-dried Ginseng: Yellowish-white. Fragments of resin canals containing yellow masses of secretion. Clusters of calcium oxalate 20–68 μm in diameter, with acute angles. Cork cells subsquare or polygonal, with thin and sinuous walls. Reticulate and scalariform vessels 10–56 μm in diameter. Starch granules fairly abundant, simple granules subspheroidal, semi-circular or irregular polygonal, 4–20 μm in diameter, hilum pointed or slit-shaped; compound granules of 2–6 components.

(2) To 0.5 g of the powder add 5 ml of ethanol, shake for 5 minutes, filter. Evaporate a small quantity of the filtrate to dryness in an evaporating dish, add dropwise a saturated solution of antimony trichloride in chloroform, evaporate to dryness again; a violet colour is produced.

(3) To 1 g of the powder add 40 ml of chloroform, heat under reflux on a water bath for 1 hour, discard the chloroform layer, evaporate the residue to dryness. Moisten the residue with 0.5 ml of water, add 10 ml of *n*-butanol saturated with water, ultrasonicate for 30 minutes. To the supernatant liquid add 3 volumes of ammonia TS, mix well, allow to stand. Evaporate the supernatant liquid to dryness, dissolve the residue in 1 ml of methanol as the test solution. Prepare a solution of 1 g of Radix Ginseng reference drug in the same manner as the reference drug solution. Dissolve ginsenosides R_{b1} , R_e , R_g1 in methanol to produce a solution containing each of 2 mg per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B), using silica gel G as the coating substance (500 μm thick) and chloroform-ethyl ac-

etate-methanol-water (15:40:22:10) as the mobile phase. Apply separately to the plate 1–2 μl of each of the three solutions. After developing and removal of the plate, dry it in air, spray with 10% solution of sulfuric acid in ethanol, heat at 105°C for several minutes. Examine under sun-light and ultra-violet light (365 nm). The spots or fluorescent spots in the chromatogram obtained with the test solution correspond in position and colour to the spots in the chromatogram obtained with the reference drug solution. The three purplish-red spots in the chromatogram obtained with the test solution under sun-light correspond in position and colour to the spots in the chromatogram obtained with the reference solution. A yellow and two orange fluorescent spots in the chromatogram obtained with the test solution under ultra-violet light (365 nm) correspond in position and colour to the spots in the chromatogram obtained with the reference solution.

Processing Sun-dried Ginseng Soften thoroughly, cut into slices, and dry.

Sun-dried Wild Ginseng Pulverize or break to pieces before use.

Action To reinforce the vital energy, to remedy collapse and restore the normal pulse, to benefit the spleen and lung, to promote the production of body fluid, and to calm the nerves.

Indications Prostration with impending collapse marked by cold limbs and faint pulse; diminished function of the spleen with loss of appetite; cough and dyspnea due to diminished function of the lung; thirst due to impairment of body fluid, of diabetes caused by internal heat; general weakness with irritability and insomnia in chronic diseases; impotence or frigidity; heart failure, cardiogenic shock.

Usage and dosage 3–9 g.

Precaution Incompatible with Rhizoma et Radix Veratri.

Storage Preserve in well closed containers, stored in a cool and dry place, protected from moth.

Radix Ginseng Rubra

(红参, Hongshen)

Red Ginseng

Red Ginseng is the steamed and dried root of the cultivar (known as "Yuansheng") of *Panax ginseng* C. A. Mey. (Fam. Araliaceae). The drug is collected in autumn, washed clean, steamed, and dried.

Description Main roots fusiform or cylindrical, 3–10 cm long 1–2 cm in diameter. Externally translucent, reddish-brown, occasionally exhibiting a few dark yellowish-brown patches; furrowed longitudinally, wrinkled and rootlet scars, upper part exhibiting interrupted indistinct annulations, lower part bearing 2–3 twisted intersected branch root and numerous curved rootlets or just showing depressed-circular stem scars (Luan), some bearing 1–2 entire or broken adventitious roots (Ding). Texture hard and fragile, fracture even, horny. Odour delicate fragrant and characteristic; taste, sweet and slight bitter.

Identification (1) Carry out the method for Identification test (1) in the monograph of Radix Ginseng. It shows the same characteristics except the starch granule.

(2) Carry out the method for Identification test (2) and (3) in the monograph of Radix Ginseng. It shows the same result.

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The first measures to be taken in case of poisoning are gastric lavage and activated charcoal instillation. All other measures proceed according to the symptoms. For loss of potassium, careful replenishment is necessary. For ectopic irritation build-up in the ventricle, administration of phenytoin as an antiarrhythmic is recommended. Lidocaine should be used in cases of ventricular extrasystole, and for partial atrioventricular block, atropine is recommended. The prophylactic installation of a pacemaker is often necessary. For elimination of the glycosides hemoperfusion is possible, the administration of cholestyramine for interrupting the enterohepatic circulation and/or the application of digitoxin antibodies (antigen-binding fragments, digitalis antidote (Boehringer Mannheim), is very likely only fully effective with digitoxin poisoning).

The drugs and pure glycosides should be administered in the following situations (among others) atrioventricular block of the 2nd and 3rd degree, hypercalcaemia, hypocalcaemia, hypertrophic cardiomyopathy, carotid sinus syndrome, ventricular tachycardia, thoracic aortic aneurysm, WPW-syndrome.

DOSEAGE

Mode of Administration: Today, the drug is obsolete. Due to the lack of reproductivity of content, the use of appropriate pure glycosides is advisable. Digitoxin is contained in mono preparations (extract) and used as an isolated pure substance.

Preparation: Tincture: shaken for 1 day in 25% ethanol at a ratio of 1:10.

The manufacture of the digoxin and digitoxin is a complicated process that involves fermentation, extraction, and evaporation.

Storage: Store carefully away from sources of light.

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Dill

See *Anethum Graveolens*

Dioscorea Villosa

Wild Yam

DESCRIPTION

Medicinal Parts: The medicinal part is the dried rhizome with the roots.

Flower and Fruit: The plant has small greenish-yellow flowers. The male flowers are in drooping panicles; the female ones in drooping spicate racemes.

Leaves, Stem and Root: *Dioscorea villosa* is a perennial vine. It has a pale brown, cylindrical, twisted, tuberous rhizome and a thin, woolly, reddish-brown stem that measures up to 12 m long. The leaves are broadly ovate, usually alternating,

cordate and 6 to 14 cm long. The upper surface is glabrous and they are pubescent beneath. The fracture is short and hard.

Characteristics: The taste is insipid at first, then acrid. The leaves are odorless.

Habitat: The plant is indigenous to the Southern U.S. and Canada. It is now widely cultivated in many parts of the world in tropical, subtropical and temperate regions.

Other Names: China Root, Colic Root, Devil's Bones, Rheumatism Root, Yuma

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Saponins: including dioscin (aglycone diosgenin)

Isoquinuclidine alkaloids: including dioscorin

EFFECTS

Anti-inflammatory, cholagogue, antispasmodic, and a mild diaphoretic.

INDICATIONS AND USAGE

Wild Yam is used for rheumatic conditions, gallbladder colic, dysmenorrhea and cramps.

Industrially used as an active agent in the half-synthesis of steroid hormones and for the manufacture of homeopathic preparations.

PRECAUTIONS AND ADVERSE REACTIONS

Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded.

OVERDOSAGE

Poisoning is conceivable with overdoses because of the microtoxin-like effect of dioscorin (see *Cocculi fructus*).

DOSEAGE

Mode of Administration: Liquid extract.

LITERATURE

Hegnauer R, *Chemotaxonomie der Pflanzen*, Bde 1-11, Birkhäuser Verlag Basel, Boston, Berlin 1962-1997.

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Dipsacus Silvestris

Teazle

DESCRIPTION

Medicinal Parts: The medicinal part is the whole flowering plant with root.

Flower and Fruit: The flowers are lilac with 8 cm long, cylindrical capitula. The bracts are lanceolate-awl-shaped, curved upwards, thorny and longer than the capitulum. The long outer bract with its straight tip is longer than the flowers. The calyx is basin-shaped and the corolla is fused with 4 tips. There are 4 stamens and 1 inferior ovary. The fruit is a nutlet.

Leaves, Stem and Root: The plant is a biennial that grows 80 to 150 cm high. The stem is erect, angular, and thorny. The basal leaves are rosette-like, crenate-serrate. The cauline leaves are oblong with a thorny midrib underneath.

Habitat: The plant grows in southern England.

Production: Common Teazle root is the underground part of *Dipsacus silvestris*.

Other Names: Barber's Brush, Brushes and Combs, Card Thistle, Church Broom, Venus' Basin

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Iridoide monoterpenes: including cantleyoside, loganin, sweroside, sylvestroside III and IV

Caffeic acid derivatives: including chlorogenic acid

EFFECTS

No information is available.

INDICATIONS AND USAGE

Teazle is used externally for small wounds, fistulae, psoriasis and as a rub in the treatment of rheumatism.

PRECAUTIONS AND ADVERSE REACTIONS

Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded.

DOSEAGE

Mode of Administration: Teazle is used externally in alcoholic extracts.

LITERATURE

Hegnauer R, *Chemotaxonomie der Pflanzen*, Bde 1-11, Birkhäuser Verlag Basel, Boston, Berlin 1962-1997.

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Dipteryx Odorata

Tonka Beans

DESCRIPTION

Medicinal Parts: The medicinal part is the bean.

In the U.S., the plant is used for gynecological disorders or "female complaints", in particular dysmenorrhea, amenorrhea and complaints associated with prolapses vaginae.

Preparations of False Unicorn Root are also used for loss of appetite, venous dyspepsia, flatulence and nervous digestive complaints. In Argentina, it is used to treat chronic bronchitis.

PRECAUTIONS AND ADVERSE REACTIONS

No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.

DOSEAGE

Mode of Administration: Available in the forms of powdered root, liquid extract and infusions for internal use.

Preparation: To prepare an infusion, 1.5 gm of the drug is added to 100 ml of water. A fluid extract (1:1) is produced with ethanol water (45%).

Daily Dosage: The recommended dose is 0.3 to 0.6 gm to be taken 3 times daily.

LITERATURE

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Alfalfa

See *Medicago Sativa*

Alisma Plantago-aquatica

Water Plantain

DESCRIPTION

Medicinal Parts: The medicinal part is the fresh rhizome.

Flower and Fruit: The peduncle is triangular. There are long-pedicled, white or reddish flowers in leafless, loose panicles. There are 3 sepals, 3 petals and 3 stamens in the

flower. The fruit is small and obtuse and is formed by 15 to 30 ovaries.

Leaves, Stem and Root: The water leaves are ribbon-like. There are long stemmed, swimming leaves. The aerial leaves are basal, long-stemmed, cordate or oblong-ovate, and spoon-like.

Characteristics: Water Plantain has a bitter taste in root-stock. It is poisonous when fresh.

Habitat: The plant is distributed widely throughout Europe, northern Asia, and North America.

Other Names: Mad-Dog Weed

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Triterpenes: including: alisol-A, alisol-B, alisol-C and their monoacetates

Sesquiterpenes

Flavone sulfate

Caffeic acid derivatives: chlorogenic acid sulfate

EFFECTS

No information is available.

INDICATIONS AND USAGE

The drug is used for diseases of the bladder and urinary tract.

PRECAUTIONS AND ADVERSE REACTIONS

No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.

DOSEAGE

Mode of Administration: The drug is available as an extract for oral use. The root is also used in homeopathy.

LITERATURE

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Alkanna Tinctoria

Alkanna

DESCRIPTION

Medicinal Parts: The medicinal part is the root of the plant (the dried roots and rhizomes).

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Wagner H, Wiesenauer M. Phytotherapie. Phytopharmaka und pflanzliche Homöopathika, Fischer-Verlag, Stuttgart, Jena, New York 1995.

Coolwort

See *Tiarella Cordifolia*

Copaiba Balsam

See *Copaifera Langsdorffi*

Copaifera Langsdorffi

Copaiba Balsam

DESCRIPTION

Medicinal Parts: The medicinal parts are the resin oil tapped from an incision in the trunk.

Flower and Fruit: The flowers are small and yellow.

Leaves, Stem and Root: *Copaifera langsdorffi* is an evergreen tree up to 18 m high with compound leaves.

Characteristics: The resin oil consists of resin and essential oil. The oleoresin ranges in viscosity from very liquid and pale yellow to a resin-like substance of a red or fluorescent tint. The taste is unpleasant and there is a characteristic smell. A single tree can yield some 40 liters.

Habitat: Indigenous to tropical regions of South America and South Africa.

Production: Copaiba balsam is extracted from *Copaifera reticulata* and other varieties.

Other Names: Copaiava

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Volatile oil: chief constituent alpha- and beta-caryophyllene, L-cadinenes, copaene

Resins: in particular diterpenoid oleoresins

EFFECTS

Possible bacteriostatic effect on the urinary tract.

INDICATIONS AND USAGE

The drug has various uses as a stimulant, laxative, and diuretic. Also used in infections of the urinary tract.

Copaiba Balsam is obsolete as a drug, however, it is still used in some homeopathic preparations.

PRECAUTIONS AND ADVERSE REACTIONS

The drug is irritating to the mucous membranes. Toxic in large amounts. Stomach pains appear after the intake of 5 gm of the drug, repeated doses bring about summer cholera, shivers, tremor, pains in the groin, and insomnia. Skin contact can lead to contact dermatitis (erythema, papular or vesicular rash, urticaria, petechias, occasionally the rashes heal leaving brown spots).

LITERATURE

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Steinegger E, Hänsel R, Pharmakognosie, 5. Aufl., Springer Verlag Heidelberg 1992.

Coptis Trifolia

Goldthread

DESCRIPTION

Medicinal Parts: The medicinal parts are the rhizome and sometimes the stems and leaves.

Flower and Fruit: The solitary flowers are small and white and are arranged on leafless scapes.

Leaves, Stem and Root: Goldthread is a perennial plant in bushes of up to 15 cm with yellowish, scaly leaves at the base and long-petioled, obovate, evergreen leaves. The rhizome is thread-like, golden yellow with a matte surface and very small roots.

Characteristics: Goldthread has a very bitter taste and slight odor.

Habitat: *Coptis trifolia* is indigenous to India and *Coptis groenlandica*, which is also used, is indigenous to Greenland and Iceland.

Production: Goldthread rhizome is the rhizome of *Coptis trifolia*.

Other Names: Mouth Root, Cankerroot, Yellowroot, *Coptis*, *Coptide*

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Isoquinoline alkaloids: including *coptin*, *berberine*

EFFECTS

The herb is a bitter tonic.

INDICATIONS AND USAGE

Goldthread is used in digestive disorders.

PRECAUTIONS AND ADVERSE REACTIONS

Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded.

DOSAGE

Mode of Administration: Internally as a powdered drug or a liquid extract.

LITERATURE

Hegnauer R. *Chemotaxonomie der Pflanzen*, Bde 1-11, Birkhäuser Verlag Basel, Boston, Berlin 1962-1997.

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Coral Root

See *Corallorhiza Odontorhiza*

Corallorhiza Odontorhiza

Coral Root

DESCRIPTION

Medicinal Parts: The medicinal parts are the roots of the parasite.

Flower and Fruit: The plant has 10 to 20 flowers in terminal panicles. The flower heads are hood-like, reddish or purplish on the outside, paler and flecked with purple lines on the inside. One petal forms a lip with purple spots and a purple rim. The fruit is a large, bent-back, ribbed, long capsule.

Leaves, Stem and Root: Coral Root is a perennial which is found growing around the roots of trees in woodlands. The rhizome is small, brown, coral-like, about 2 to 3 cm long and 2 mm in thickness, with minute warts and transverse scars. The fracture is short and horny.

Characteristics: The taste is sweetish then bitter, the odor strong and peculiar when fresh.

Habitat: The parasite is indigenous to the U.S.

Production: Coral Root is the rhizome of *Corallorhiza odontorhiza*.

Other Names: Crawley Root, Scaly Dragon's Claw, Chicken Toe, Crawley, Fever Root, Turkey Claw

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Unknown

EFFECTS

Coral Root has diaphoretic, febrifuge, and sedative effects.

INDICATIONS AND USAGE

Coral Root is used for colds. It is very efficient at inducing perspiration. Its scarcity prevents its wider use.

PRECAUTIONS AND ADVERSE REACTIONS

Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded.

DOSAGE

Mode of Administration: Internally as a liquid extract.

LITERATURE

No literature is available.

Coriander

See *Coriandrum Sativum*

Coriandrum Sativum

Coriander

DESCRIPTION

Medicinal Parts: The medicinal parts are the coriander oil and dried ripe fruit.

INDICATIONS AND USAGE

The drug is used for digestive disorders, flatulence, and dysmenorrhea.

PRECAUTIONS AND ADVERSE REACTIONS

No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.

DOSAGE

Mode of Administration: Ground drug is used as an infusion.

LITERATURE

Kern W, List PH, Hörhammer L (Hrsg.), Hagers Handbuch der Pharmazeutischen Praxis, 4. Aufl., Bde. 1-8. Springer Verlag Berlin, Heidelberg, New York, 1969.

Moneywort

See Lysimachia Nummularia

Monkshood

See Aconitum Napellus

Morus Nigra

Black Mulberry

DESCRIPTION

Medicinal Parts: The medicinal parts are the ripe berries and the root bark.

Flower and Fruit: The plant is monoecious or dioecious. The greenish flowers are in catkin-like inflorescences. The male ones are ovate to cylindrical, the female ones are ovate or globular. The flowers have a 4-bract involucre, which enlarges and becomes fleshy in the female flowers. The female flowers have 2 stigmas, the male ones have 4 stamens. All the fruit from the catkins develop into blackberry-like false berries (which are really a series of fleshy drupes). They are edible and pleasant-tasting.

Leaves, Stem and Root: The tree grows from 6 to 12 m. The bark is gray brown. The leaves are alternate with flat-grooved, somewhat hairy petioles. They are cordate or ovate, unevenly lobed, and serrate with short rough hairs above.

Habitat: The plant is cultivated worldwide in temperate regions.

Other Names: Purple Mulberry, White Mulberry

ACTIONS AND PHARMACOLOGY**COMPOUNDS IN THE FRUIT**

Fruit acids (1.9%): including among others malic acid, citric acid

Saccharose (10%)

Pectins

Ascorbic acid (0.17%)

Flavonoids: including, among others, rutin

COMPOUNDS IN THE LEAVES

Flavonoids: including among others rutin (2-6%)

The constituents of the rhizome rind are not known.

EFFECTS

The active agents are sugar, acids, pectin, and rutin.

INDICATIONS AND USAGE

The drug is used as a mild laxative and in the treatment of respiratory catarrh.

PRECAUTIONS AND ADVERSE REACTIONS

No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.

DOSAGE

Mode of Administration: The drug is used internally.

Daily Dosage: The average daily dose is 2 to 4 ml of syrup.

LITERATURE

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Oliver-Bever B (Ed.), Medicinal Plants of Tropical West Africa, Cambridge University Press, Cambridge 1986.

Motherwort

See Leonurus Cardiaca

Mountain Ash Berry

See Sorbus Aucuparia

Not To Be Confused With: *Berula erecta* or *Cardamine amara*.

Other Names: Indian Cress

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Glucosinolates in the fresh, unbruised plant: chief components gluconasturtiin, releasing mustard oil through destruction of cells, releasing phenylethylisothiocyanate, additionally including among others, glucotropaeolin (producing benzyl isothiocyanat)

Flavonoids

Vitamin C (80 mg/100 gm)

EFFECTS

Watercress has antibiotic and diuretic actions. The diuretic effect is probably due to the mustard oil content.

INDICATIONS AND USAGE

■ Cough/bronchitis

The plant is used for catarrh of the respiratory tract. In folk medicine, it is used as an appetite stimulant and for digestion complaints because of its bitter taste. Because of its Vitamin C content, it is used as a spring tonic. A decoction of the leaves in poultices and compresses for arthritis and rheumatoid arthritis is used in the folk medicine of northeastern Italy.

CONTRAINDICATIONS

Contraindications include stomach or intestinal ulcers and inflammatory renal diseases.

PRECAUTIONS AND ADVERSE REACTIONS

General: No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages. The intake of large quantities of the freshly-harvested plant, for example in salad, could lead to gastrointestinal complaints due to the mucous membrane-irritating effect of the mustard oil.

Pediatric Use: The drug should not be administered to children under 4 years old.

DOSEAGE

Mode of Administration: The comminuted herb, freshly-pressed juice, as well as other galenic preparations of the plant are for internal use.

Preparation: In folk medicine, the comminuted drug can be taken directly. To make an infusion, pour 150 ml boiling water over 2 gm drug (1 to 2 teaspoonfuls), cover for 10 minutes and strain.

Daily Dosage: The daily dosage is 2 to 3 cups of the infusion before meals, 4 to 6 gm of the dried herb, 20 to 30 gm of the

fresh herb, or 60 to 150 gm of freshly-pressed juice. Externally, the drug is applied as a poultice or a compress.

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Nelumbo Nucifera

Lotus

DESCRIPTION

Medicinal Parts: The medicinal parts are the roots, the seeds, and the aerial parts of the flowering plant.

Flower and Fruit: The solitary flowers are 16 to 23 cm across, pink and scented. They grow above the leaves. The seeds are 1.7 by 1.3 cm and ovoid.

Leaves, Stem and Root: The rhizome is 10 to 20 cm long, stout, and branching. It bears numerous scale-like leaves as well as foliage leaves. The foliage leaves are peltate and have no sinuses. The petioles are 1 to 2 cm long, the lamina are 30 to 100 cm in diameter and are almost circular, glossy, and unwettable.

Habitat: The plant is indigenous to India.

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Isoquinoline alkaloids: including, among others, roemerin, nuciferin, normuciferin, liensinine, isoliensinine, neferine, lotusine, arnepavin, liriodenine, asimilobin

Flavonoids: including, among others, hyperoside, isoquercitrin, quercetin glucuronide, camphor glucuronide

Tannins

EFFECTS

Active agents are the alkaloids "nelumbin" and roemerin, in the leaves. The drug is an astringent.

INDICATIONS AND USAGE

The powdered beans are used in the treatment of digestive disorders, particularly diarrhea. The flowers are used as an astringent for bleeding.

PRECAUTIONS AND ADVERSE REACTIONS

No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.

DOSEAGE

Mode of Administration: Preparations of the plant are available in powder and liquid extract form.

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Nepeta Cataria

Catnip

DESCRIPTION

Medicinal Parts: The medicinal parts are aerial parts of the plant collected during the flowering season.

Flower and Fruit: The inflorescence is spike-like and the lower verticillasters distant from each other. The small individual flowers are on short pedicels. The bracts are 1.5 to 3 mm and linear-awl-shaped. The sepals are 5 to 6.5 mm long and ovate. The tips are 1.5 to 2.5 mm long, linear-lanceolate and patent. The corolla is 7 to 10 mm long, is slightly longer than the calyx and is white with small purple spots.

Leaves, Stem and Root: The root of the plant is perennial. The stems are up to 1 m high, angular, erect and branched. They are leafy gray-pubescent to tomentose giving the whole plant a whitish gray appearance. The leaves are 2 to 8 cm, ovate, cordate at the base, crenate or serrate and gray-tomentose beneath. The petiole is 0.5 to 4 cm in length.

Characteristics: Aromatic, characteristic smell, reminiscent of Mint and Pennyroyal.

Habitat: Indigenous to Europe and naturalized in the U.S.

Production: Catnip is the aerial part of *Nepeta cataria*. The harvesting takes place in uncultivated regions. The drug is manually cut in dry and sunny weather conditions. The woodless parts of the plant are sorted out and the material is then left to dry in the shade.

Other Names: Catnep, Catrup, Catmint, Catswort, Field Balm

ACTIONS AND PHARMACOLOGY**COMPOUNDS**

Volatile oil (0.2-0.7%): chief components are nepetalactone (share 80-95%), additionally including among others epinepentalactone, caryophyllene, camphor, thymol, carvacrol

EFFECTS

Active agents are bitter and tannin substances, as well as essential oil. Antipyretic, refrigerant, relieves cramps, sedative, diaphoretic. The tea has a diuretic effect and increases gallbladder activity.

INDICATIONS AND USAGE

Colds, colic, also for the treatment of nervous disorders and migraine, since preparations from the mint have a calming effect. It is also used in the treatment of gynecological disorders. *Nepeta cataria* has a long tradition in England and France as a kitchen and medicinal herb and was used occasionally as stimulating drink until the introduction of black tea.

PRECAUTIONS AND ADVERSE REACTIONS

No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.

DOSEAGE

Mode of Administration: Orally in ground and dried forms.

Preparation: To prepare an infusion (tea), add 10 teaspoons per liter of water, leave this to stand and draw for 10 minutes.

Daily Dosage: Drink 2 to 3 cups of the tea daily.

LITERATURE

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*Catechin tannins***EFFECTS**

Stimulation of the secretion of saliva and gastric juices.

INDICATIONS AND USAGE

- Loss of appetite
- Dyspeptic complaints

Cinchona bark is used to correct loss of appetite, dyspepsia and flatulence with a sense fullness. In folk medicine, the bark is used for malaria, flu, enlarged spleen, muscle cramps, cancer, and gastric disorders. Externally it is used for scrapes and leg ulcers.

PRECAUTIONS AND ADVERSE REACTIONS

General: Sensitization to quinine and quinidine have been observed (eczema, itching). Even with therapeutic dosages, an enhanced pseudo-hemophilia can occur by the drug triggering thrombocytopenia.

Drug Interactions: Because of the possibility of thrombocytopenia, care must be taken when Cinchona preparations are administered along with other drugs that are known to precipitate thrombocytopenia.

OVERDOSAGE

In cases of overdosage (over 3 g quinine) or of long-term administration of the drug or its alkaloids, nausea, summer cholera, headache, fall of body temperature, intravascular hemolysis, cardiac arrhythmias, buzzing in the ears, hearing and visual disorders (all the way to complete deafness and blindness) may occur. Death comes with dosages of 10 to 15 g of quinine through heart failure and asphyxiation. Following gastric lavage, the symptomatic therapy for acute poisonings includes atropine for bradycardia and phenytoin in the presence of tachycardic heart rhythm disorders. Forced diuresis and hemodialysis are not suitable as therapeutic measures.

DOSAGE

Mode of Administration: Comminuted drug and other bitter-tasting galenic preparations to be taken internally.

Preparation: An infusion is prepared by pouring boiling water over 1/2 teaspoonful of the drug and allowing to draw for 10 minutes. A decoction is prepared by adding 0.5 g to 1 teacup of water. A tincture in the proportion of 1:5 in 75% ethanol is also used.

Other preparations involve various complicated extraction processes.

Daily Dosage: Total daily dose is 1 to 3 g of drug. The liquid extract daily dose is 0.6 to 3 g of cinchona liquid extract, which contains 4 to 5% total alkaloids. A daily dose of 0.15 to 0.6 g cinchona extract with 15 to 20% total alkaloids may also be used.

The standard single dose of the extract is 0.2 g. The liquid extract single dose is 0.5 to 1 g.

Storage: Keep protected from light and moisture.

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Cinnamomum Aromaticum

Chinese Cinnamon

DESCRIPTION

Medicinal Parts: The medicinal parts are the flowers collected and dried after they have finished blossoming, the

young twigs and whole or partly peeled, dried bark of thin branches as well the oil extracted from them and the young dried branches.

Flower and Fruit: The flowers are small and are on short, slender, silky pedicels. They are arranged in threes in cymous panicles in the leaf axils and in larger panicles at the end of the branches. The perianth is slightly silky, about 3 mm long, with oblong-lanceolate petals. The fruit is a juicy, pea-sized, ellipsoid, smooth drupe.

Leaves, Stem and Root: Evergreen tree up to 7 m tall with aromatic bark and angular branches. The bark is brown, in quilled pieces, sometimes with the remains of the outer layer present. The 7.5 to 10 cm long leaves are oblanceolate and are on 6 to 8 cm long petioles and are pubescent and more or less tapered towards the base. They are coriaceous, alternate and are brown underneath.

Habitat: Indigenous and cultivated in southern China, Vietnam and Burma.

Production: Chinese cinnamon consists of the completely or partly peeled, dried stem bark from the above ground axis of *Cinnamomum aromaticum*. The drug comes from 2 to 3 cm thick branches; it is peeled with horn knives and freed from cork and outer rind and dried in the sun within 24 hours.

Not To Be Confused With: Waste products from the production process or other barks and materials.

Other Names: Cassia, False Cinnamon, Bastard Cinnamon, Cassia Lignea, Cassia Bark, Cassia aromaticum, Canton Cassia

ACTION AND PHARMACOLOGY

COMPOUNDS

Volatile oil: chief components cinnamaldehyde, weiterhin cinnamylacetate, cinnamyl alcohol, o-methoxycinnamaldehyde, cinnamic acid, coumarin

Diterpenes

Tannins

Oligomere proanthocyanidins

Mucilages

EFFECTS

Antibacterial, fungistatic, improves immunity in animal tests, promotes motility, inhibits ulcers.

INDICATIONS AND USAGE

- Loss of appetite
- Dyspeptic complaints
- Fevers and colds
- Cough/bronchitis
- Tendency to infection

- Inflammation of the mouth and pharynx
- Common cold

Loss of appetite, dyspeptic complaints such as mild, colicky upsets of the gastrointestinal tract, bloating, flatulence; used in the symptomatic treatment of gastrointestinal disorders, temporary states of exhaustion and to increase weight.

Used in Chinese medicine for impotence, diarrhea, enuresis, rheumatic conditions, testicle hernia, menopause syndrome, amenorrhoea, abortion and to stabilize immunity.

PRECAUTIONS AND ADVERSE REACTIONS

General: No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages. The drug possesses a medium potential for sensitization. Sensitizations to cinnamaldehyde occur frequently.

Pregnancy: The drug is not to be administered in time of pregnancy.

DOSEAGE

Mode of Administration: Comminuted bark for infusions; essential oil, as well as other galenic preparations for internal use.

Preparation: Tincture of cinnamon: moisten 200 parts cinnamon bark evenly with ethanol and percolate to produce 1000 parts tincture.

Daily Dosage: 2 to 4 g drug; 0.05 to 0.2 g essential oil; Average single dose: 1 g.

Storage: Cool, dry conditions in well-sealed containers.

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Cinnamomum Camphora

Camphor Tree

DESCRIPTION

Medicinal Parts: The medicinal part is camphor oil extracted from the tree.

Flower and Fruit: The flowers are small and white and are on 1 to 1.5 mm long pedicles. The petals are pubescent on the inside. The flowers are in long-peduncled axillary panicles. The stamens form 3 circles, are 1.5 mm long, pubescent with broad, sessile-cordate glands. The fruit is a purple-black, 1-seeded, 10 to 12 mm oval drupe.

Leaves, Stem and Root: The plant is an evergreen tree growing up to 50 m tall and 5 m in diameter. The trunk is erect at the lower part and is knottily branched above. The leaves are 5 to 11 cm long by 5 cm across, oval-lanceolate, alternate, acuminate, grooved, glossy and light yellowish green above, paler beneath.

Habitat: Found from Vietnam to southern China as far as southern Japan.

Production: Purified camphor is obtained from the wood of the camphor tree *Cinnamomum camphora* using steam distillation followed by sublimation.

Other Names: Gum Camphor, Laurel Camphor, Cemphire.

ACTION AND PHARMACOLOGY

COMPOUNDS

Camphora is a single substance: D(+)-camphor ((1R,4R)-1,7,7-Trimethyl-bicyclo[2.2.1]heptan-2-on), extracted from the volatile oil of the trunk of the camphor tree, *Cinnamomum camphora*. L(-)-camphor also occurs in nature. Synthetic camphor is DL-camphor.

EFFECTS

External: bronchial secretolytic, hyperemic.

Internal: circulatory tonic, respiratory analeptic, bronchial antispasmodic.

INDICATIONS

- Cardiac insufficiency NYHA I and II
- Arrhythmia

- Hypertension
- Hypotension
- Nervous heart complaints
- Rheumatism

External: muscular rheumatism, catarrhal diseases of the respiratory tract, cardiac symptoms.

Internal: hypotonic circulatory regulation disorders, catarrhal diseases of the respiratory tract.

PRECAUTIONS AND ADVERSE REACTIONS

General: Local administration can lead to skin irritation, as well as to resorbent and/or airborne poisonings. Contact eczema occasionally appears following the application of oily salves containing camphor.

Pediatric Use: Camphor salves should not be administered to infants.

OVERDOSAGE

Symptoms of poisonings that have been seen particularly in children, include intoxicated states, delirium, spasms and respiratory control disturbances. Treatment proceeds symptomatically. The lethal dosage for children is approximately 1 g, for adults approximately 20 g (toxic dosage of camphor is 2 g).

DOSEAGE

Mode of Administration: Locally or for inhalation; in liquid or semisolid form. Internally, in liquid or solid preparations.

Daily Dosage: Internal average daily dosage: 30 to 300 mg. For external use, depending on prescribed application, generally in concentrations of not higher than 25%, for small children not higher than 5%.

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Pagoda Tree

See *Sophora Japonica*

Panax Ginseng

Ginseng

DESCRIPTION

Medicinal Parts: The medicinal part is the dried root.

Flower and Fruit: The inflorescence is simple or branched with 1 to 3 umbels of 15 to 30 flowers. The flowers are androgynous and have greenish-yellow corollas. The ovary is inferior. The fruit is a pea-sized, globose to reniform, scarlet, smooth and glossy drupe, which contains 2 seeds.

Leaves, Stem and Root: The plant is perennial, erect and 30 to 80 cm high. It has a glabrous, round stem and bears terminal whorls of 3 to 5 palmate leaves. The leaflets are thin, finely serrate, gradually acuminate, 7 to 20 cm long and 2 to 5 cm wide. The plant has a fusiform rhizome, which is often palmate at the tip giving it a human-like form.

Habitat: *Panax ginseng* is indigenous to China. It is cultivated in China, Korea, Japan and Russia. *Panax quinquefolius* grows in the U.S.

Production: Ginseng root consists of the dried main and lateral root and root hairs of *Panax ginseng*.

Other Names: American Ginseng, Chinese Ginseng, Korean Ginseng

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Triterpene saponins

Aglycone (20S)-protopanaxadiol: including ginsenoside Ra1, Ra2, Ra3, Rb1, Rb2, Rb3, notoginsenoside R4, Rs1, Rs2, malonylginsenoside Rb1, Rc, Rd

Aglycone (20S)-protopanaxatriol: including ginsenoside Re, Rf, Rg1, notoginsenoside R1

Aglycone oleanolic acid: including ginsenoside Ro, chikusetsusaponin-V

Water-soluble polysaccharides: panaxane A to U

Polyyenes: including faltarinol (panaxynol), faltarintriol (panaxytriol), examples esterified with acetic acid or linolenic acid

EFFECTS

The main active agent is ginsenoside. In various stress models, (immobilization test and the coldness test), the resistance of laboratory rodents was increased.

INDICATIONS AND USAGE

■ Lack of stamina

Ginseng is also used as a tonic for invigoration and fortification in times of fatigue and debility and for declining capacity to work and concentrate. It is also used during convalescence.

PRECAUTIONS AND ADVERSE REACTIONS

Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded.

OVERDOSAGE

Massive overdoses can bring about Ginseng Abuse Syndrome, which is characterized by sleeplessness, hypertension and edema.

DOSAGE

Mode of Administration: Comminuted drug infusions, powder and galenic preparations for internal use. Various standardized preparations containing ginseng root are available.

Preparation: To make an infusion, pour boiling water over 3 gm comminuted drug and strain after 5 to 10 minutes.

Daily Dosage: The average daily dosage is 1 to 2 gm root. The infusion may be taken 3 to 4 times a day over 3 to 4 weeks.

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The Tan Sheet

Vol. 7; No. 26; Pg. 17

June 28, 1999

SECTION: THE NEWS THIS WEEK

LENGTH: 133 words

TITLE: DIETARY SUPPLEMENT STRUCTURE/FUNCTION CLAIMS: METAGENICS

TEXT:

Company..... Metagenics
 Product/Ingredient.. Metabotanica Licorice Plus
 Date..... 4/12/99
 Description..... "Adrenal support formula"; "Licorice is an herb with an unparalleled reputation for promoting health and longevity. Its ability to support adrenal hormone metabolism is associated with one of the herb's key components, glycyrrhizic acid"; "Ashwagandha, often referred to as 'Indian ginseng,' is an Ayurvedic herb with renowned adaptogenic properties"; "Chinese yam and rehmannia are traditionally used to tonify kidney 'yin' and are associated with health and vitality"; "An herbal adaptogen complex designed to support adrenal and immune function."



LOAD-DATE: July 6, 1999



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AMRION

1332 '99 MAR 23 P2 118

February 22, 1999

3/12/99

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

NOTIFICATION OF STATEMENTS OF NUTRITIONAL SUPPORT

This Notification is filed pursuant to § 403(r)(6) of the Federal Food Drug and Cosmetic Act (FDC Act), 21 U.S.C. §343 (r)(6).

Name of dietary supplement: PharmaLogics Echinacea-Goldthread

Statements of
nutritional support:

Increase Immune Protection; Echinacea and Goldthread are two of the best-known herbal supplements for immune system support. This combination adds powerful defense to your immune system.

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

AMRION, INC.

Terese Maltzman
Terese Maltzman, Ph.D.
Research Scientist

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The Tan Sheet

Vol. 7; No. 16; Pg. 23

April 19, 1999

SECTION: THE NEWS THIS WEEK

LENGTH: 224 words

TITLE: DIETARY SUPPLEMENT STRUCTURE/FUNCTION CLAIMS: PERFORMANCE LABS

TEXT:

Company..... Performance Labs
 Product/Ingredient.. ImmuMax
 Date..... 2/9/99
 Description..... "Naturally boosts your body's defenses";
 "Nutritional defense health formula";
 "ImmuMax combines the herbs and
 micronutrients most closely associated with
 healthy immune system function"; "ImmuMax's
 powerful formula uses Echinacea DX with 8%
 phenolic compounds - double the amount of
 standard extracts - in combination with the
 herbs and micronutrients most closely
 associated with immune system vitality.
 Clinical studies have demonstrated their
 effectiveness in supporting the body's
 natural defenses-without unpleasant side
 effects"; "Echinacea - extensive German
 research has demonstrated the powerful
 immune system support of this North
 American wildflower"; "Goldenseal - this
 Native American plant, known for its
 health-promoting properties, is especially
 effective when used in combination with
 echinacea"; "Goldthread - like goldenseal,
 goldthread contains beneficial alkaloids
 that support the body's natural defenses";
 "Astragalus - an important Chinese herb
 with a 2,000-year-old reputation as an
 immune system tonic."

LOAD-DATE: April 26, 1999



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4(47): 12-34

November 18, 1996

SECTION: THE NEWS THIS WEEK

LENGTH: 11009 words

TEXT:

WEIDER MODIFIES "VIRUS RESISTANCE," "CANCER" SUPPLEMENT CLAIMS after FDA sent a July 30 "courtesy" letter. In response to FDA's notification that the claims do not meet the structure/function claim standards established in the Dietary Supplement Health & Education Act, Weider Nutrition Group has changed its claims for the two products -- Schiff All Natural Echinacea Cold Season Formula and Schiff Phytocharged Lycopene.

Weider "will immediately cease distribution of the Echinacea product label, and submit another structure/function claim to be included on the new label," the company said in an Aug. 8 response. The Lycopene product had not been distributed as of Aug. 8, so the firm was able to modify labeling prior to distribution.

The firm's original claim for Schiff All Natural Echinacea Cold Season Formula, filed in February, was: "Echinacea root extracts may improve [the] number and functions of immune system cells in humans. Resistance to viruses may be enhanced." The revised claim, registered Aug. 9, reads: "Echinacea is a traditional Native American herb most frequently used during the cold, winter months. Echinacea supports healthy immune system function."

Registered in March, the claim for Schiff Phytocharged Lycopene stated: "Eating a diet high in tomatoes and foods rich in tomato extracts (tomato sauce) has been related to a lower risk of prostate and other cancers." Following the July 30 letter from FDA, Weider Nutrition filed the amended claim on Aug. 9: "Eating a diet high in tomatoes and foods rich in tomato extracts (tomato sauce) has been linked to improved health and well-being."

The second part of the claim -- "Tomatoes contain lycopene, a carotenoid that is an efficient defense against singlet oxygen, a molecule that damages cells" -- remains unchanged.

Weider told FDA it would "welcome the opportunity to receive feedback" from FDA as the company "continue[s] to interpret how to write structure/function claims" as allowed by DSHEA. "Obviously," the company said, "there are some areas of overlap between nutrient functions or their effects on body structures and health claims. We appreciate this period of interaction in order to more fully comply with your interpretation of health claims."

Weider said it filed the claims with FDA as "test cases," seeking a "clear interpretation" from the agency of what constitutes a structure/function claim. Weider said it has filed "hundreds" of structure/function claims with FDA and is



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in the process of filing additional claims; so far, FDA has objected only to the two claims cited, the company said.

FDA also took issue with claims for two products filed by Bruce EnviroExcel Group on behalf of the dietary supplement manufacturer Sanimpex. In response to the agency's June 24 letter, Sanimpex revised the names of two products and the claim made for one, detailing the changes in a July 18 response.

Sanimpex' Bioseve 17/Articular Problems was renamed Bioseve 17/Joint Functions. The name Bioseve 29/Infection was changed to Bioseve 29/Resistance. The claim for the product originally said: "Dietary supplement to nutritionally support a sense of well-being in people with head and chest infections." Sanimpex changed the claim to read: "Dietary supplement to nutritionally support normal immune system functions."

FDA has flagged a number of dietary supplement companies' structure/function claims as inappropriate. Firms receiving letters from the agency include: Global Marketing International, J.B. Harris, Pacific BioLogic, Emord & Associates (acting on behalf of an unnamed client), Nature's Life, Nutritional Support Systems and Action Labs ("The Tan Sheet" July 29, p. 8).

Action Labs, in a June 5 letter, informed FDA that it changed a statement of nutritional support for Echinacea/Golden Seal to read: "Helps promote well-being during cold and flu season" and began distributing the newly labeled product on July 1. FDA had censured the firm for making the claim: "For relief of symptoms of cold, flu and sore throat," pointing out that under the FD&C Act, the company "may not claim to diagnose, mitigate, treat, cure or prevent a specific disease of class of diseases."

DIETARY SUPPLEMENT STATEMENTS OF NUTRITIONAL SUPPORT

[Submitted to FDA under the Dietary Supplement Health & Education Act and compiled by F-D-C Reports from information recently made available by the agency.]

Company	Product/Ingredient	Claim	Date
Abkit	NatureWorks Betatene	"Scientific studies have shown that regular consumption of carotenes helps maintain a strong healthy immune system"	8/9/96
Abkit	NatureWorks Activated C	"Supports healthy immune function as the body ages"; "Alpha Lipotene [alpha lipoic acid] recycles and re-powers vitamin C, returning it to its potent state to make its benefits last longer"	8/9/96
Abkit	NatureWorks Activated E	"Supports healthy heart function as the body ages"; "Alpha Lipotene [alpha lipoic acid] recycles and re-powers vitamin E to make its benefits last longer"	8/9/96
Abkit	NatureWorks Alpha Lipotene	"Protects you against all 8	8/9/96



Herbs		health"	
Frontier	Fo-ti Root	"Oriental longevity herb"	9/9/96
Herbs			
Frontier	Garlic	"Promotes healthy	9/9/96
Herbs		cholesterol levels"	
Frontier	Ginger Root	"Promotes digestion,	9/9/96
Herbs		natural antioxidant"	
Frontier	Ginkgo Leaf	"Support for healthy memory	9/9/96
Herbs		function"	
Frontier	Ginseng Root-American;	"Supports endurance and	9/9/96
Herbs	Ginseng Root-Korean	stamina"	
Frontier	Goldenseal Root	"Enhances seasonal	9/9/96
Herbs		resistance"	
Frontier	Gotu Kola Herb	"Support for healthy memory	9/9/96
Herbs		function"	
Frontier	Hawthorn Berries	"Support for healthy heart	9/9/96
Herbs		function"	
Frontier	Hop Flowers	"Naturally promotes	9/9/96
Herbs		relaxation"	
Frontier	Horseradish Root	"Support for healthy	9/9/96
Herbs		digestive system"	
Frontier	Kava Kava Root	"South Pacific calming	9/9/96
Herbs		herb"	
Frontier	Marshmallow Root	"Soothing internal	9/9/96
Herbs		botanical"	
Frontier	Milk Thistle Seed	"Supports healthy liver	9/9/96
Herbs		function"	
Frontier	Motherwort Herb	"Female body balancer"	9/9/96
Herbs			
Frontier	Nettle Leaf	"Blood builder,	9/9/96
Herbs		multi-mineral source"	
Frontier	Passion Flower Herb	"Naturally promotes	9/9/96
Herbs		relaxation"	
Frontier	Peppermint Leaf	"Soothing aromatic for head	9/9/96
Herbs		and digestion"	
Frontier	Pleurisy Root	"Support for healthy lung	9/9/96
Herbs		function"	
Frontier	White Willow Bark	"Support for head	9/9/96
Herbs		well-being"	
Frontier	Wild Yam Root	"Traditional women's herb"	9/9/96
Herbs			
Frontier	Yarrow Flowers	"Support during cold and	9/9/96
Herbs		flu season"	
Frontier	Yellowdock Root	"Traditional purifying	9/9/96
Herbs		tonic"	
Frontier	Yerba Santa Leaf	"Support for healthy	9/9/96
Herbs		respiratory function"	
Frontier	Yucca Root	"Support for healthy joint	9/9/96
Herbs		function"	
Futurebiotics A & D		"Utilized in the	3/20/96
		maintenance of tissue	
		structure, proper vision	
		and bone and teeth	
		formation"	



absorbed, 20% increase in metabolism equivalent, 5.5% improvement in anaerobic threshold, 37% increase in stroke volume per heart beat"; "Researchers at Guiyang University believe Elixir of Youth and FemVitale may have a positive effect on coronary health, enhance cognitive performance, promote evening serenity and help maintain good bowel health"; "Chinese studies have shown FemVitale exhibited a variety of biological activities to promote premenstrual and menopausal support and cycle regulation"; "(Panoxides) support and regulate the female hormonal system"; "Dong Quai, known as the women's Ginseng, also works with Jiaogulan as a tonic for the female reproductive system"

Good Earth	Ginseng SportICE (regular and caffeine-free)	"Enhances physical endurance"; "Naturally enhance your daily exercise program"	4/9/96
Gumtech International	Chroma Trim	"[Chromium picolinate] has been shown in double blind clinical studies to assist in promoting the reduction of fat and the increase of lean muscle tissue"	5/20/96
Gumtech International	Jack LaLanne's Power Gum	"Helps maintain stamina and stimulates metabolism"	5/20/96
Gumtech International	Jack LaLanne's Ginseng Gum	"Helps maintain overall good health and promotes strength and endurance"	5/20/96
Gumtech International	Jack LaLanne's Digestive Gum	"Designed to aid digestion"	5/20/96
Gumtech International	Jack LaLanne's Diet Gum	"Studies show can curb appetite"	5/20/96
Gumtech International	Citrus Slim	"Assists in delivering HCA to the liver which can positively influence the use of calories early in meals. The result? You eat less, yet feel	5/20/96



Natrol	Migra Help with Feverfew	"Inhibits the production of substances called prostaglandins in the body"	8/2/96
Natrol	Protection Formula One with Echinacea Extract	"Supporting defense system functions"; "Promoting microbial balance"	8/2/96
Natrol	Protection Formula Two with Golden Seal Foot Extract	"Supporting health"; "Promoting microbial balance"; "Promoting activity of white blood cells, a key component in immune function that helps maintain optimal health"	8/2/96
Natrol	Siberian Power with Siberian Ginseng	"Enhances physical and mental resistance to environmental stress, while fortifying general endurance"	8/2/96
Natrol	Joint Herb with Devils Claw Extract	"Supporting fluid and joint function"	8/2/96
Natrol	Cardio-Herb with Hawthorn Berry Extract	"Has very promising attributes for supporting normal heart function"	8/2/96
Natrol	Kidney Support Formula with Uva Ursi	"Positive support of the urinary tract"	8/2/96
Natrol	Parafight Formula with Artemisia	"When combined with a balanced diet, adequate water intake and probiotic supplementation with L. acidophilus, a natural, live culture of beneficial micro-organisms -- Parafight helps support digestive health"	8/2/96
NaturaLife	Activated Charcoal	"One of the finest natural absorbent agents known"; "Each particle contains many small chambers and cavities that capture or bind up unwanted materials and gas"; "The charcoal then carries it safely through the system"	3/18/96
NaturaLife	Feverfew Leaf	"Scientific studies on the parthenolide content of feverfew have identified its role in helping to maintain normal blood vessel tone"	3/18/96
NaturaLife	Chamomile Flowers	"Relaxes digestive tract"	3/20/96
NaturaLife	Cayenne Ginger Combination	"Stimulates digestion"	3/20/96
NaturaLife	Cold Defense Formula	"Promotes well-being during the cold and flu season"	4/1/95
NaturaLife	Ginseng	"Enhances mental endurance"	4/1/96



NaturaLife	Garlic	and vitality" "In clinical studies, garlic has been shown to lower serum cholesterol and help maintain circulatory efficiency"	4/1/96
NaturaLife	Saw Palmetto	"Promotes prostate health"; "Clinical studies with our exclusive extract show that it helps maintain proper urinary flow in men over 50"	4/1/96
NaturaLife	Restful Night Formula	"Promotes restful sleep"	4/1/96
NaturaLife	Urinary Tract Formula	"Helps maintain a healthy urinary tract"	4/1/96
Natural Organics	MigraActin	"Nutritionally support the body's normal adaptogenic function"	4/31/96
Natural Organics	ImmunActin	"Nutritionally support the body's normal adap- togenic function"	8/3/96
Natural Organics	OcuActin	"Nutritional support for ocular [function]"	8/3/96
Naturally Vitamin Supple- ments	Naturally Fem Berries	"Supports normal urinary tract function"	3/11/96
Naturally Vitamin Supple- ments	Naturally Phosphotidyl Ginkgo Boost;	"Supports normal brain function"	3/11/96
Naturally Vitamin Supple- ments	Naturally Tyroserine Plus Naturally Maxi Flav	"Flavonoid antioxidant support"	3/11/96
Naturally Vitamin Supple- ments	Naturally Mello Kava	"Supports restful sleep"	3/11/96
Naturally Vitamin Supple- ments	Naturally Saw Palmentto	"Supports normal prostate function"	3/11/96
Naturally Vitamin Supple- ments	Lycoplex Naturally 20/20	"Supports normal eyesight"	3/11/96
Nature Food Centres	Nutra Flora FOS	"Helps friendly bacteria such as bifidobacterium, lactobacillus acidophilus and lactobacillus bulgaricus to flourish in the intestines"	4/22/96



Nature's Herbs	Milk Thistle Phytosome	"Nutritionally supports healthy liver function"	7/18/96
Nature's Herbs	Ginseng Phytosome	"Nutritionally supports healthy adaptogenic function"	7/19/96
Nature's Herbs	Saw Palmetto & Beta Sitosterol-Power	"Nutritionally supports healthy prostate function"	7/20/96
Nature's Herbs	Super Prostate-Power	"Nutritionally supports healthy prostate function"	7/21/96
Nature's Herbs	Saw Palmetto & Pygeum-Power	"Nutritionally supports healthy prostate function"	7/22/96
Nature's Life	Calcium Softgel	"For strong bones and healthy teeth"	3/12/96
Nature's Life	Cranberry Concentrate	"Helps to protect the bladder by inhibiting the adherence of bacteria to the bladder wall"	3/12/96
Nature's Life	Lutein	"Helps to protect the retina against oxidative damage"	3/12/96
Nature's Life	Echinacea	"Stimulate the production of white blood cells"; "Stimulates wound healing by increasing fibroblasts (blood-clotting cells)"; "In Europe, echinacea preparations are used to maintain good health during cold and flu seasons"	3/12/96
Nature's Life	Grape Seed Extract	"Potent antioxidant free radical scavengers"	4/9/96
Nature's Life	Lycopene	"Protects cells from oxidative damage"; "Neutralizes singlet oxygen more efficiently than vitamin E or beta carotene and is concentrated in the prostate gland"	4/9/96
Nature's Life	Vitamin C Powder	"A powerful antioxidant to help protect and maintain cellular health"	5/2/96
Nature's Life	Ginkgo Biloba Extract	"Increases blood flow to the brain, enhancing mental function and also inhibits free-radical oxidation of cell membranes"	6/3/96
Nature's Life	Men's Formula 800+	"To nourish and maintain a healthy prostate"	6/3/96
Nature's Life	Formula 600 Plus for Men	"Helps to maintain a	9/9/96



Rexall Sundown	B Vitamins	function" "For a healthy nervous system"; "Helps maintain healthy muscle and heart function"	6/11/96
Rexall Sundown	Calcium	"Helps to maintain a regular heartbeat"; "Maintains strong bones and healthy teeth"; "Helps maintain healthy cardiovascular function"	6/11/96
Rexall Sundown	Echinacea and Golden Seal	"Promotes general well being during the cold and flu season and helps support a healthy immune system"	6/11/96
Rexall Sundown	Feverfew	"Helps reduce cellular inflammation"	6/11/96
Rexall Sundown	Garlic	"Helps promote healthy cardiovascular function"; "Helps maintain cholesterol and blood pressure levels"	6/11/96
Rexall Sundown	Hawthorne Berries	"Helps maintain heart rhythm and blood pressure function"	6/11/96
Rexall Sundown	Lutein with Zeaxanthin	"Helps maintain healthy eye function"	6/11/96
Rexall Sundown	Lycopene	"Promote healthy cell structure and protect against oxidative cell damage"	6/11/96
Rexall Sundown	Vitamin A	"Helps in maintaining healthy cholesterol levels"; "Assists proper cardiovascular function"; "Assists in the proper function of the immune system"; "Promotes healthy eye function"	6/11/96
Rexall Sundown	Vitamin C	"For general well-being during the cold and flu season"; "Essential for free radical protection"; "Helps maintain healthy blood cholesterol levels"; "Helps promote immune function"	6/11/96
Rexall Sundown	Vitamin E	"Helps prevent free radical damage to body cells"; "Helps maintain proper circulatory	6/11/96



Food and Drug Administration
Office for Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

3/24/99

4477 '99 APR -7 09:55

March 23, 1999

NOTIFICATION OF DIETARY SUPPLEMENT CLAIMS

Manufacturer Name and Address: Perrigo Company of South Carolina 117 Water St. Allegan, MI 49010	
Statement Text: Promotes vitality & well-being.	
Dietary Ingredient: Panax Ginseng	Dietary Supplement Name: MULTI VITAMIN WITH GINSENG CAPLET
Appears on the following labels:	
GOOD SENSE	PERRIGO DAILY SOURCE

I hereby certify that the information presented and contained in this notice is complete and accurate.

I also certify that Perrigo Company has substantiation to verify that the statement is truthful and not misleading.

Heidi Horn
Heidi Horn

March 23, 1999
(Date)

Dietetics Pharma International, Inc

7599 Redwood Blvd., Suite 214 * Novato, CA 94948
Phone: 415-892-5988 / Fax: 415-893-8159

May 12, 1999

7419 65988 MAY 26 1999



Certified Mail / Return Receipt Requested
Office of Special Nutritionals (HFS-450)
CF SAN
U.S. Food & Drug Administration
200 "C" Street, S.W.
Washington, D.C. 20204

To Whom It May Concern:

This letter is to provide notification of the structure/function statements that appear on our nutritional supplements product labels. The product line is called *2-Phase Activated Nutrients™* and the individual products within this line are Energy Tonic, Probiotic Balance, Memory Tone, and Immun-O Guard. The general statement for the entire product line is as follows; "*2-Phase Activated Nutrients™* provides superior results compared to capsules/tablets or liquids alone. This advanced technological application (combining solids with liquids immediately before consumption) provides excellent bioavailability and better absorption resulting in faster, more effective results."

The structure/function statements for each of the four individual products within the *2-Phase Activated Nutrients™* product line are as follows...

Energy Tonic (with Ginseng & Creatine):

"To maximize performance, boost energy, and combat fatigue and stress" and "Energy Tonic is designed to maximize performance, boost energy, and combat fatigue and stress by supporting vessels and supplying energy nutrients."

* Ingredients about which the claim is made: Panax Ginseng (root), Creatine, Carnosine, Ginkgo biloba extract, Thiamin (Vitamin B-1), Riboflavin (Vitamin B-2), Vitamin B-6, and Vitamin B-12.

Probiotic Balance (with L. acidophilus):

"Helps to maintain healthy balance of the intestinal flora" and "Probiotic Balance provides 5 billion friendly bacteria per serving. Probiotics (meaning: for life) describe a group of beneficial bacteria that are essential for proper digestion and used to promote overall good health. Friendly flora helps to support the immune system."

* Ingredients about which the claim is made: L. sporogenes, L. bulgaricus, L. lactis, L. acidophilus, L. ramosus, B. bifidum, S. thermophilus, Thiamin (Vitamin B-1), Riboflavin (Vitamin B-2), Vitamin B-6, and Vitamin B-12.

Memory Tone (with Ginkgo biloba):

"To support memory and alertness" and "Memory Tone supports memory and alertness by helping to: increase circulation, strengthen protective barriers and deliver supportive nutrients to the brain."

* Ingredients about which the claim is made: DL-Phosphatidylserine, L-glutamine, Centella asiatica extract (leaf), Ginkgo biloba extract, Vitamin A (as beta-carotene), Vitamin E (as L-alpha tocopherol), Echinacea purpurea extract (root), and Red Orange Concentrate (fruit).

Immun-O Guard (with Echinacea):

"Supports healthy immune system" and "Powerful antioxidant activity from Red Orange Concentrate (ROC), along with other nutritive supports, can help increase the body's natural defense system."

* Ingredients about which the claim is made: Echinacea angustifolia extract (root), Echinacea purpurea extract (root), Red Orange Concentrate (fruit), Selenium (as selenium yeast), Vitamin A, Vitamin C, and Zinc (as zinc pidolate).

The Distributor of the above-mentioned products is....

Dietetics Pharma International, Inc.
7599 Redwood Blvd., Suite 214
Novato, CA 94945
Phone: 415-892-5988
Toll Free: 800-946-3100
Fax: 415-893-8159

The Manufacturer of the above-mentioned products is....

Dietetics Pharma s.r.l.
Via Mecenate 84,12
20138 Milano, Italy
Phone: 011-39-02-50-62101
Fax: 011-39-02-580-12471

The information contained in this notice is complete and accurate. Dietetics Pharma International, Inc. has substantiation that the statements for the products mentioned in this letter are truthful and not misleading.

Should you have any further questions or concerns, please contact us at Dietetics Pharma International, Inc., 7599 Redwood Blvd., Suite 214, Novato, CA 94945; Phone: 415-892-5988, Fax: 415-893-8159. Thank you.

Sincerely,
Thilo Koeler
Dietetics Pharma International, Inc.

By: _____
Thilo Koeler
Vice President

11TH ARTICLE of Level 1 printed in FULL format.

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The Tan Sheet

Vol. 7; No. 5; Pg. 12

February 1, 1999

SECTION: THE NEWS THIS WEEK

LENGTH: 179 words

TITLE: DIETARY SUPPLEMENT STRUCTURE/FUNCTION CLAIMS: PURE ENCAPSULATIONS

TEXT:

Company..... Pure Encapsulations

Product/Ingredient.. **Panax Ginseng** 27/30

Date..... 10/15/98

Description..... "**Panax ginseng** has long been utilized to assist the body in adapting to physical and emotional stress"; "During prolonged exercise, **Panax ginseng** promotes endurance and stamina by sparing carbohydrates and allowing skeletal muscle to oxidize free fatty acids for energy production"; "**Panax ginseng** also encourages adrenal gland health in times of stress by maintaining normal levels of certain adrenal hormones, most notably, corticosterone"; "This versatile herb promotes male reproductive health by supporting testosterone and spermatozoa levels"; "In addition, **Panax ginseng** promotes memory and learning, and nutritionally supports immune function and cardiovascular health"; "**Panax ginseng** helps the body adapt to its environment by enhancing endurance and adrenal gland health."

LOAD-DATE: February 8, 1999



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NOTIFICATION

On Statement of Nutritional Support Made on the Label of a Dietary Supplement

Nature's Essence™ Menopause Nutrient P2308

Notification to: Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition,
Food and Drug Administration
200 C St SW
Washington, DC 20204



From: Mount Spring International Corp.
403 West 51 Street, Suite 5
New York, NY 10019
Telephone: (212) 956-4608, Fax (212) 977-3672, e-mail dzhang@mtspring.com
Contact: Daqun Zhang, Ph.D., President.

Date: April 9, 1999

1 The name and address of the company of the dietary supplement that bears the statement:

Mount Spring International Corp.
403 West 51 Street, Suite 5
New York, NY 10019

2. The text of the statement

"Clinically proved safe & effective nutrient supporting menopause & bone health"

"Nature's Essence™ Menopause Nutrient supports menopause & bone health via its beneficial effects on the liver, the kidney, the endocrine system & health of blood compositions."

3 List of ingredients of the dietary supplement *Nature's Essence™ Menopause Nutrient*

English Name	Latin Name
Fleece flower root	Redix polygoni multiflori
Fleece flower stem	Caulis Polygoni multiflori
Wheat	Tritici fructus
Uncaria	Ramulus uncariae cum uncis
Scrophularia	Redix scrophulariae
Rehmannia	Redix rehmanniae

Poria
Nacre
✓Alisma

Poria
Concha margaritifera usta
Rhizoma alismatis

4. The name and brand name of the dietary supplement on whose label the statement appears

The name: Menopause Nutrient
Brand name: *Nature's Essence*™

5. Signature and Certification of the accuracy

This notice is signed by:

Signature:



Name printed and title: Daqun Zhang, Ph.D., President

Certification

I, the undersigned, certify that the information contained in the notice is complete and accurate.

Signature:



Name printed and title: Daqun Zhang, Ph.D., President