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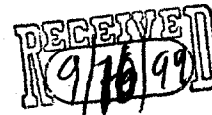
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VIA HAND DELIVERY

September 16, 1999

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 Sir or Madam:

This notification is being filed pursuant to section 403(r)(6) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 343(r)(6), and in accordance with the requirements of 21 C.F.R. § 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: DIALUPSTON™

Dietary Ingredients: Loosestrife (Jin-Qian-Cao) (*Lysimachia christinae*) (herb)^{1/}
Capillary Artemisia (Yin-Chen) (herb)
Chinese Rhubarb (Da-Huang) (root)
Asian Psyllium (herb)
Baikal Skullcap (Huang-Qin) (root)
Costus (Mu-Xiang) (root)
Turmeric, curcuma (fruit)
Magnolia Bark (Hou-Po) (cortex)

^{1/} Journ. Bot. London 11:167 1873.

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LET 4428

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**Structure/Function
Statements:**

1. This product supports and helps to regulate the functioning of the gallbladder.
2. This product helps to clean the colon and maintain a healthy digestive tract.

These effects on the structure and function of the body arise from the proprietary blend of dietary ingredients present in DIALUPSTON™, which is a modified formulation of Lidan Paishi Pian containing Loosestrife (Jin-Qian-Cao) (*Lysimachia christinae*), Capillary Artemisia (Yin-Chen), Chinese Rhubarb (Da-Huang), Asian Psyllium, Baikal Skullcap (Huang-Qin), Costus (Mu-Xiang), Turmeric, curcuma, and Magnolia Bark (Hou-Po).

Summary of Substantiation:

The claims "supports and helps to regulate the functioning of the gallbladder" and "helps to clean the colon and maintain a healthy digestive tract" for the proprietary blend in DIALUPSTON™, a modified formulation of Lidan Paishi Pian, are based on, and supported by, reference to authoritative scientific literature, and the existence of the previously notified/permitted claims for selected ingredients in DIALUPSTON™.

The Pharmacopoeia of the People's Republic of China,^{2/} which is approved by the Ministry of Public Health of the People's Republic of China, states that Lidan Paishi Pian is comprised, in part, of seven of the above dietary ingredients, and is produced through a specific manufacturing procedure.^{3/} The Pharmacopoeia of the People's Republic of China states that the action of Lidan Paishi Pian is "[t]o remove damp-heat, increase the flow of bile and expel

2/ The Pharmacopoeia Commission of PRC, Pharmacopoeia of the People's Republic of China (Chemical Industry Press, English ed. 1997) (Chinese ed. 1995).

3/ Id. at 313-14. (copy attached).

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calculi” and that Lidan Paishi Pian is indicated for “[c]holelithiasis, infection of the biliary tract, cholecystitis.”^{4/}

In addition, the Pharmacopoeia of the People’s Republic of China and the Physicians Desk Reference for Herbal Medicines^{5/} state information, such as indications, about the component ingredients that comprise DIALUPSTON™. For example, the Pharmacopoeia of the People’s Republic of China states the following actions and indications for the component ingredients of Lidan Paishi Pian:

- Loosestrife (Jin-Qian-Cao) (*Lysimachia christinae*) (herb)
Action: “[t]o remove damp-heat, relieve dysuria”; Indications: “[a]cute urinary infection or urolithiasis with difficult painful urination; jaundice with dark urine, hepatic or biliary calculus.”^{6/}
- Capillary Artemisia (Yin-Chen) (herb)
Action: reduces heat in the blood; Indication: relieves jaundice.^{7/}
- Chinese Rhubarb (Da-Huang) (root)
Action: “[t]o cause catharsis and purge away heat”; Indications: “[f]ever with constipation, retention of the feces and abdominal pain; dysentery with inadequate discharge from the bowels.”^{8/}

4/ Id. at 314 (italics omitted).

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

6/ Pharmacopoeia of the People’s Republic of China, supra note 2, at 98 (italics omitted) see PDR for Herbal Medicines, supra note 5, at 951-52.

7/ Pharmacopoeia of the People’s Republic of China, supra note 2, at 85.

8/ Id. at 149-50 (italics omitted); PDR for Herbal Medicines, supra note 5, at 1092 (affects motility of colon and indicated for constipation).

- Asian Psyllium (herb)
Indications: "diarrhea caused by summerdamp."^{9/}
- Baikal Skullcap (Huang-Qin) (root)
Action: "[t]o remove damp-heat, to quench fire and counteract toxicity";
Indications: "feeling of stuffiness in the abdomen, acute dysentery or jaundice caused by damp-heat."^{10/}
- Costus (Mu-Xiang) (root)
Actions: "relieve pain by promoting the flow of qi, and to improve digestion by reinforcing the spleen function"; Indications: epigastric pain; tenesmus in dysentery; indigestion associated with anorexia.^{11/}
- Turmeric, curcuma (fruit)
Actions: promotes the flow of qi (i.e., energy) and increases the flow of bile;
Indications: distending or pinching abdominal pain, or jaundice with dark urine.^{12/}

9/ Pharmacopoeia of the People's Republic of China, *supra* note 2, at 100 (italics omitted); PDR for Herbal Medicines, *supra* note 5, at 1049 (psyllium indicated for habitual constipation).

10/ Pharmacopoeia of the People's Republic of China, *supra* note 2, at 170 (italics omitted).

11/ Id. at 143 (italics omitted).

12/ Pharmacopoeia of the People's Republic of China, *supra* note 2, at 146; *see* PDR for Herbal Medicines, *supra* note 5, at 787 (choleric, cholikinetic affects; indicated for gallbladder complaints).

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- Magnolia Bark (Hou-Po) (cortex)
Action: "eliminate damp and relieve distension"; Indications: "[a]ccumulation of damp in the spleen and the stomach," and abdominal distension and constipation.^{13/}

FDA has previously been notified of, and has permitted, claims similar to, or related to, the proposed claims for certain of the ingredients in DIALUPSTON™. Specifically, notified and permitted structure/function claims include the following:

- for psyllium: "helps clean the colon";^{14/}
- for psyllium: "helps maintain a healthy digestive tract";^{15/}
- for rhubarb: "to promote daily regularity . . . promot[e] the movement of chi in the body and dispers[e] heat";^{16/}
- for rhubarb: "Bowel Regularity Formula," "help maintain normal stool softness," "help maintain normal stool moisture content and normal stool softness," and "[p]rovides . . . support for the lower colon ch'i";^{17/}

^{13/} Pharmacopoeia of the People's Republic of China, *supra* note 2, at 31 (italics omitted); see PDR for Herbal Medicines, *supra* note 5, at 953 (magnolia indicated for digestive disorders).

^{14/} Dietary Supplement Structure/Function Claims: General Nutrition, F-D-C Rep. ("The Tan Sheet"), Mar. 1, 1999, at 17; Dietary Supplement Structure/Function Claims: GNC, F-D-C Rep. ("The Tan Sheet"), Sept. 28, 1998, at 16.

^{15/} F-D-C Rep. ("The Tan Sheet"), Sept. 28, 1998, at 16.

^{16/} Dietary Supplement Structure/Function Claims: BMK International, F-D-C Rep. ("The Tan Sheet"), Aug. 31, 1998, at 18.

^{17/} Kim Krumhar, Ph.D., Metagenics, Notification Letter to FDA, at 6 and 9 (Apr. 12, 1999).

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- for turmeric: "Liver and gallbladder support, traditionally used to balance the energy (ch'i) of the liver and abdominal area"^{18/}; and
- for rhubarb, skullcap, and magnolia bark: "promote health of gastrointestinal system and helps maintain normal defecation."^{19/}

Therefore, the proposed claims "supports and helps to regulate the function of the gallbladder" and "helps to clean the colon and maintain a healthy digestive tract" are proper and supportable for the proprietary blend in DIALUPSTON™, a modified Lidan Paishi Pian Mixture containing, among other ingredients, Turmeric, curcuma, Asian Psyllium, Chinese Rhubarb, Baikal Skullcap and Magnolia Bark.

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

Sincerely,



Stephen Paul Mahinka
Counsel for Uniweal, Ltd.

Enclosures

^{18/} Id. at 3 and 8.

^{19/} Daqun Zhang, Ph.D., Nature's Essence, Notification Letter to FDA, at 1-2 (Apr. 9, 1999).

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

This Pharmacopoeia is the English version edited from Pharmacopoeia of the People's Republic of China 1995 edition. The Chinese edition is approved by the Ministry of Public Health of the People's Republic of China to be effective from April 1, 1996, in accordance with the official document WYF (95) 77.

(京)新登字 039 号

图书在版编目(CIP)数据

中华人民共和国药典 一部: 英文版/郭济贤主编.

北京: 化学工业出版社, 1997. 12

ISBN 7-5025-2062-7

I. 中... II. 郭... III. 药典-中国-英文 IV. R921.2

中国版本图书馆 CIP 数据核字(97)第 22567 号

Compiled by The Pharmacopoeia Commission of PRC

ISBN 7-5025-2062-7 / R·28

Copyright 1997 by Chemical Industry Press

Published by the Chemical Industry Press

No. 3, Huixinli, Chaoyang Dist., Beijing, China, 100029

Printed in the People's Republic of China

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MONOGRAPHS

PART I

**Chinese Materia Medica,
Oil, Fats, etc.**

strip correspond to the spot of the reference substance, comply with the method as described under the preparation of standard calibration, beginning at the word "to stoppered conical flasks. ..." Measure the absorbance, read out the concentration from the standard curve, and calculate. It contains not less than 1.36% of esculin ($C_{12}H_{16}O_6$).

Processing Eliminate foreign matter, wash clean, soften thoroughly, cut inot slices, and dry in the sun.

Action To remove damp-heat, to arrest discharges, and to improve eyesight.

Indications Acute dysentery and diarrhea; morbid leukorrhea; inflammation of the eye; nebula.

Usage and dosage 6-12 g; for external use, appropriate quantity to be decocted for washing.

Storage Preserve in a ventilated and dry place.

Cortex Illici

(地枫皮, Difengpi)

Difengpi Bark

Difengpi Bark is the dried stem bark of *Illicium difengpi* K. I. B. et K. I. M. (Fam. Magnoliaceae). The drug is collected in spring and autumn, and dried in the sun or at a low temperature.

Description Quilled or channelled, 5-15 cm long, 1-4 cm in diameter, 2-3 mm thick. The outer surface greyish-brown or dark-brown, some showing greyish-white patches of lichens. Coarse bark easily exfoliated or fallen off, the exposed layer brownish-red. The inner surface brown or brownish-red, with distinct fine longitudinal wrinkles. Texture lax and fragile, easily broken, fracture granular. Odour, slightly aromatic; taste, slightly astringent.

Identification (1) Transverse section: Cork consisting of several rows of cells, the inner walls relatively thick, containing reddish-brown substances. Cortex scattered with groups of stone cells, parquous with a few fibre bundles; secretory cells present. Phloem rays of 1 row of cells, also showing secretory cells, but smaller than those in cortex. Parenchymatous cells containing reddish-brown substances and starch granules.

(2) To 2 g of the coarse powder add 5 ml of chloroform, shake, macerate for 30 minutes, and filter. Spot the filtrate to filter paper. After drying, examine under ultra-violet light (254 nm), a scarlet to pale scarlet fluorescence is produced.

Processing Eliminate foreign matter, wash clean, break to pieces, and dry in the sun.

Action To relieve rheumatic conditions, and to promote the flow of qi and relieve pain.

Indications Rheumatic arthralgia, lumbar muscle strain.

Usage and dosage 6-9 g.

Storage Preserve in a dry place.

Cortex Lycii

(地骨皮, Digupi)

Chinese Wolfberry Root-bark

Chinese Wolfberry Root-bark is the dried root bark of *Lycium chinense* Mill. or *Lycium barbarum* L. (Fam. Solanaceae). The root is collected in early spring or late autumn, and washed clean. Then the root bark is stripped, and dried in the sun.

Description Quilled or channelled, 3-10 cm long, 0.5-1.5 cm wide, 1-3 mm thick. Outer surface greyish-yellow to brownish-yellow, rough with irregular longitudinal fissures, easily exfoliated. Inner surface yellowish-white to greyish-yellow, relatively even, with fine longitudinal wrinkles. Texture light and fragile, easily broken, fracture uneven, outer layers yellowish-brown and inner layers greyish-white. Odour, slight; taste, sweetish and then bitter.

Identification Transverse section: Cork consisting of 4-10 or more rows of cells, thicker rhytidome present. Most phloem rays 1 row of cells wide; fibres singly scattered, or 2 to several in bundles. Parenchymatous cells containing sand crystals of calcium oxalate and numerous starch granules.

Total ash Not more than 11.0% (Appendix IX K).

Processing Eliminate foreign matter and remains of wood, wash clean, and dry in the sun.

Action To reduce heat in blood, to relieve consumptive fever, and to remove heat from the lung.

Indications Afternoon fever and night sweating in consumptive diseases; cough, hemoptysis and epistaxis due to heat in the lung; diabetes caused by internal heat.

Usage and dosage 9-15 g.

Storage Preserve in a dry place.

Cortex Magnoliae Officinalis

(厚朴, Houpo)

Official Magnolia Bark

Official Magnolia Bark is the dried stem bark, root bark and branch bark of *Magnolia officinalis* Rehd. et Wils. or *Magnolia officinalis* Rehd. et Wils. var. *biloba* Rehd. et Wils. (Fam. Magnoliaceae). The drug is collected from April to June. The root bark and the branch bark are dried in the shade. The stem bark is slightly decocted in boil water and piled up in a wet place until its inner surface purplish-brown or brown, steamed to rolled, and dried.

Description Stem bark Quilled singly or double quilled, 30-35 cm long, 2-7 mm thick, commonly known as "Tongpo"; one end near the root spread out like a bell, 13-25 cm long, 3-8 mm thick, commonly known as "Xue-tongpo". Outer surface greyish-brown, rough, sometimes scaled, easily exfoliated, with distinct elliptical lenticles

and longitudinal wrinkles, appearing yellowish-brown when the coarse outer layer peeled; inner surface purplish-brown or dark purplish-brown, relatively smooth, with fine longitudinal striations and exhibiting oily traces on scratching. Texture hard, uneasily broken, fracture granular, greyish-brown in outer layer and purplish-brown or brown in inner layer, oily, sometimes numerous small bright spots visible. Odour, aromatic; taste, pungent and slightly bitter.

Root bark (Genpo) Quilled singly or pieced irregularly, some curved like chicken intestines, commonly known as "Jichangpo". Texture hard, easily broken, fracture fibrous.

Branch bark (Zhipo) Quilled singly, 10–20 cm long, 1–2 mm thick. Texture fragile, easily broken, fracture fibrous.

Identification (1) Transverse section: Cork consisting of over 10 rows of cells, sometimes rhytidome found. The outer side of cortex showing a ring of stone cells and the inner side scattered with numerous oil cells and groups of stone cells. Phloem rays 1–3 rows of cells wide; fibres mostly several in bundles; oil cells scattered.

Powder: Brown. Fibres numerous, 15–32 μm in diameter, walls strongly thickened, sometimes undulate or serrate at one side, lignified, pit canals indistinct. Stone cells sub-square, elliptical, ovate, or irregularly branched, 11–65 μm in diameter, sometimes striations visible. Oil cells elliptical or subrounded, 50–85 μm in diameter, containing yellowish-brown oily contents.

(2) To 0.5 g of the powder, add 5 ml of methanol, stopper well, shake for 30 minutes, and filter. The filtrate is used as the test solution. Dissolve magnolol CRS and honokiol CRS in methanol to produce a mixture 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-methanol (27:1) as the mobile phase. Apply separately to the plate 5 μl of each of the two solutions. After developing and removal of the plate, dry it in air, and spray with 1% solution of vanillin in sulfuric acid, heat at 100°C for about 10 minutes. The spots in the chromatogram obtained with the test solution correspond in position and colour to the spots in the chromatogram obtained with the reference solution.

Assay Magnolol reference preparation Dissolve magnolol CRS, accurately weighed, dried over phosphorous pentoxide to constant weight, in ethanol to produce a solution of 20 μg per ml.

Honokiol reference preparation Perform the procedure in the same manner, as described above.

Test preparation Weigh accurately about 1 g of the powder (through No. 3 sieve), perform a determination of water (Appendix IX H, method 2), add accurately 25 ml of ethanol, heat under reflux for 1 hour, cool and filter. Discard the initial filtrate, collect the successive filtrate as the test solution.

Procedure Carry out the method for thin layer chromatography (Appendix VI B), using silica gel GF₂₅₄ as the coating substance and benzene-methanol (9:1) as the mobile phase. Apply accurately in strips separately to the plate 100 μl of the test solution (the test solution of root bark should be previously diluted with ethanol to 1/2 of its original concentration) and 5 μl of the reference solution obtained under Identification test (2) at a distance of 1.5 cm apart. After developing and removal of the plate, dry it in air and examine under ultra-violet light (254 nm). Scrape off separately the corresponding strips due to magnolol CRS, honokiol CRS and of an equal area of silica gel GF₂₅₄ on the

same plate as the blank, transfer to 10 ml centrifugal tubes respectively. Add accurately 10 ml of ethanol to each tube, stir for 10 minutes and centrifuge. Carry out the method for spectrophotometry (Appendix V A), measure the absorbances of the supernatant of the test solution, the reference solutions of magnolol and of honokiol at 294 nm, calculate the contents of magnolol and honokiol accordingly. It contains not less than 3.0% of the total amount of magnolol ($\text{C}_{15}\text{H}_{18}\text{O}_2$) and honokiol ($\text{C}_{15}\text{H}_{16}\text{O}_2$), calculated on the dried basis.

Processing Cortex Magnoliae Officinalis Scrape off the coarse outer layer, wash clean, soften thoroughly, cut into slivers, and dry in the sun.

The slivers curved, fracture fibrous, outer surface yellowish-brown, inner surface dark purplish-brown.

Cortex Magnoliae Officinalis (processed with ginger) Stir-fry the slivers of Cortex Magnoliae Officinalis as described under the method for stir-frying with ginger juice (Appendix II D) to dryness.

The slivers curved, fracture fibrous, externally purplish-brown.

Action To eliminate damp and relieve distension.

Indications Accumulation of damp in the spleen and the stomach marked by epigastric stiffness, vomiting and diarrhoea; abdominal distension and constipation due to retention of undigested food; cough and dyspnoea caused by retained damp.

Usage and dosage 3–9 g.

Storage Preserve in a ventilated and dry place.

Cortex Meliae

(苦楝皮, Kulianni)

Szechwan Chinaberry Bark

Szechwan Chinaberry Bark is the dried stem bark or root bark of *Melia toosendan* Sieb. et Zucc. or *Melia azedarach* L. (Fam. Meliaceae). The drug is collected in spring and autumn, dried in the sun as such or after removal of the coarse outer layer.

Description Irregularly tabular, channelled or semiquilled, varying in length and width, 2–6 mm thick. Outer surface greyish-brown, rough, with interwoven longitudinal wrinkles and dotted greyish-brown lenticels, yellowish when the coarse outer layer is peeled; inner surface whitish or pale yellow. Texture tough, uneasily broken, fracture fibrous, laminated, easily separated. Odourless; taste, bitter.

Identification (1) Choose any section of the drug, when folded and rubbed with hands it may be laminated, the lamination appearing alternately yellow and white layers with each lamina minutely reticulated.

(2) Macerate about 1 g of the powder with 10 ml of ether for 2 hours with constant shaking, and filter. Evaporate 1 ml of the filtrate to dryness, add several drops of p-dimethylaminobenzaldehyde T.S. dropwise; a red colour is produced. Evaporate 1 ml of the filtrate to dryness in a test tube, add 1 ml of acetic anhydride, stir, add several drops of sulfuric acid along the tube wall; a green colour in acetic anhydride layer and a red to purple colour in sulfuric acid layer are produced.

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

Action To repel worms and cure dermatosis.

slightly bitter.

Identification To about 3g of the powder add 50 ml of ethanol, heat under reflux for 1 hour, filter, evaporate the filtrate to dryness, dissolve the residue in 5 ml of ethanol and use it as the test solution. Prepare a reference drug solution of *Radix Aristoloshiae* in the same way as that described for the test solution. Dissolve aristolochic acid 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 V B), using silica gel G containing sodium carboxymethyl cellulose as the coating substance and benzene-methanol-glacial acetic acid (5:0.8:0.1) as the mobile phase. Apply separately 5 μ l of each of the above three solutions to the plate. After developing and removal of the plate, dry it in air. Examine under daylight and ultra-violet light (255 nm). The spots in the chromatogram obtained with the test solution correspond in position and colour to the spots in the chromatogram obtained with the reference solution and the reference drug solution.

Processing Eliminate foreign matter, spray with water, soften briefly, cut into sections and dry in the sun.

Action To remove summer-heat, to relieve consumptive fever, and to stop malarial attacks.

Indications Fever caused by summer-heat; afternoon fever in deficiency of yin or in consumptive diseases; malaria with chills and fever; jaundice.

Usage and dosage 4.5–9 g.

Storage Preserve in a cool and dry place.

Herba Artemisiae Scopariae

(茵陈, Yinchen)

Virgate Wormwood Herb

Virgate Wormwood Herb is the dried seedling of *Artemisia scoparia* Waldst. et Kit. or *Artemisia capillaris* Thunb. (Fam. Compositae). The drug is collected in spring when the seedling is 6–10 cm high, or in autumn when the bud is forming, removed from foreign matter and older stem, and dried in the sun. The spring-drug collected in spring is known as "Mianyinchen" and that collected in autumn is known as "Yinchenhao".

Description *Mianyinchen* Mostly rolled into masses, greyish-white, or greyish-green, densely covered with white pubescences throughout, soft like a nap. Stems thin and small, 1.5–2.5 cm long, 1–2 mm in diameter, longitudinal striations distinct after removing the white pubescences on the surface; texture fragile, easily broken. Leaves petioled, when whole, 1–3 pinnatipartite, lamina 1–3 cm long, about 1 cm wide; segments ovoid or slightly oblanceolate, stripe-shaped, apex acute. Odour, delicately aromatic; taste, slightly bitter.

Yinchenhao Stems cylindrical, frequently branched, 30–100 cm long, 2–8 mm in diameter; externally pale purple or purple, striated longitudinally, pubescent; light, texture fragile, fracture whitish. Leaves densely gathered, or mostly fallen off. Basal leaves 2–3 pinnatipartite, segments stripe-shaped or finely stripe-shaped, densely covered with white pubescences on both surfaces; cauline leaves 1–2 pinnatipartite, amplexicaul at the base, segments filamentous; capitulum ovoid, mostly gathered into

conical, 1.2–1.5 mm long, 1–1.2 mm in diameter, short petioled; involucre 3–4 layers, ovoid, bracts 3–lobed; the outer female flowers 6–10, up to 15, the inner bisexual flowers 2–10; achenes oblong, yellowish-brown. Odour, aromatic; taste, slightly bitter.

Processing Eliminate remains of roots and the foreign matter, rub or cut into pieces. For Mianyinchen, sift to remove dust.

Action To remove damp-heat and relieve jaundice.

Indications Infectious icteric hepatitis; sores with exudation and itching.

Usage and dosage 6–15 g; for external use, appropriate quantity to be made into hot decoction for fuming and washing.

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

Herba Asari

(细辛, Xixin)

Manchurian Wildginger

Manchurian Wildginger is the dried herb of *Asarum heterotropoides* Fr. var. *mandshuricum* (Maxim.) Kitag., *Asarum sieboldii* Miq. var. *seoulense* Nakai or *Asarum sieboldii* Miq. (Fam. Aristolochiaceae). The former two are known as "Liaoxixin". The drug is collected at the fruiting stage in summer or in early autumn, removed from adhering soil, and dried in the shade.

Description *Herb of Asarum heterotropoides var. mandshuricum* Usually rolled into a loose mass. Rhizomes of horizontal growth irregularly cylindrical, short-branched, 1–10 cm long, 2–4 mm in diameter; externally greyish-brown, rough, with ringed nodes, internodes 2–3 mm long, marked with dishlike stem scars at the top of a branch. Roots slender, closely born at nodes, 10–20 cm long, 1 mm in diameter; externally greyish-yellow, smooth or longitudinally wrinkled, with fibrous roots or scars. Basal leaves 1–3, long-petioled, surface glabrous; lamina mostly broken, the whole ones cordate to reniform-cordate, margins entire, acute at the apex and deeply cordate at the base, 4–10 cm long, 6–12 cm wide, surface pale green. Some with flowers, mostly crumpled, campanulate, dark purple, perianth-lobes incurved at the base and almost appressed to the perianth-tube. Fruit hemigloboid. Odour, pungent-aromatic; taste, pungent with tongue-numbing feeling.

The rhizomes of cultivated forms much-branched, 5–15 cm long, 2–6 mm in diameter. Roots 15–40 cm long, 1–2 mm in diameter; more leaves present.

Herb of Asarum Sieboldii var. Seoulense Rhizomes 1–5 mm in diameter, internodes 0.1–1 cm long. Basal leaves mostly 2, petioles hairy, lamina thicker. Perianth-lobes spread out. Fruit hemigloboid.

Herb of Asarum Sieboldii Rhizomes 5–20 cm long, 1–2 mm in diameter, internodes 0.2–1 cm long, basal leaves 1–2, lamina thinner, cordate, acuminate at the apex. Perianth-lobes spread out. Fruit subgloboid. Odour and taste relatively weak.

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

ly furrowed longitudinally on four sides, 50–100 cm long, 2–6 mm in diameter; externally yellowish-green or purplish, nodes apparently purple, white-tomentose, texture fragile, fracture yellowish-white, pith hollowed. Leaves opposite, short petiole; lamina mostly crumpled, when whole, lanceolate or oblong, 5–10 cm long; the upper surface blackish-green, the lower surface greyish-green and densely glandular-dotted, pubescent on both surfaces; apex acute, margins serrate. Flowers yellowish-brown, aggregated in leaf axils in verticillate cymes, corolla mostly fallen off, bracts and calyx persistent. Odourless; taste, weak.

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

Action To activate blood circulation and eliminate blood stasis, and to induce diuresis.

Indications Menstrual disorders, amenorrhea, dysmenorrhea, postpartum abdominal pain due to blood stasis; edema.

Usage and dosage 6–12 g.

Storage Preserve in a ventilated dry place.

Herba Lycopodii

(伸筋草, Shenjincao)

Common Clubmoss Herb

Common Clubmoss Herb is the dried whole plant of *Lycopodium japonicum* Thunb. (Fam. Lycopodiaceae). The drug is collected in summer and autumn, when foliage branch growing luxuriantly, removed from foreign matter, and dried in the sun.

Description Stolons thin-cylindrical, slightly curved, up to 2 m long, 1–3 mm in diameter, with yellowish-white rootlets underneath. Erect stems bifurcated. Leaves densely growing on the stems, spirally arranged, crumpled and curved, linear or needle-shaped, 3–5 mm long, yellowish-green to pale yellowish-brown, glabrous, aristate at the apex, margin entire, easily broken. Texture soft, fracture pale yellow in bark and whitish in wood. Odourless; taste, weak.

Identification (1) Transverse section of stems: Epidermal cells 1 row. Cortex broad, scattered with leaf trace bundles, bearing 10–20 or more rows of sclerenchymatous cells below the epidermis and outside the stele respectively and 3–5 rows of parenchymatous cells with slightly thickened walls between them; endodermis indistinct. Pericycle consisting of several rows of parenchymatous cells, plecostele, bundles of xylem irregularly stripe-shaped or branched intermingled with bundles of phloem, some cells containing yellowish-brown masses.

(2) To 3 g of the powder add 30 ml of ethanol, heat under reflux for 20 minutes and filter. Evaporate the filtrate to dryness, add 10 ml of 1% hydrochloric acid solution to the residue, stir and filter. Adjust the filtrate to pH 8 with ammonia TS, extract with 10 ml of chloroform, evaporate the chloroform extract to dryness and dissolve the residue in 5 ml of 1% hydrochloric acid solution. Transfer 1 ml of each of the above solution to 2 test tubes, add 2 drops of potassium iodobismuthate iodide TS to one tube, an orange-red precipitate is produced; add 2 drops of silicotungstic acid TS to the other, a white precipitate is produced.

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

Action To relieve rheumatic conditions and muscular contracture.

Indications Arthralgia with limited mobility of the joints.

Usage and dosage 3–12 g.

Storage Preserve in a dry place.

Herba Lysimachiae

(金钱草, Jinqiancao)

Christina Loosestrife

Christina Loosestrife is the dried herb of *Lysimachia christinae* Hance (Fam. Primulaceae). The drug is collected in summer and autumn, removed from foreign matter, and dried in the sun.

Description Frequently twisted into masses, glabrous or sparsely pubescent. Stems twisted, externally brown or dark brownish-red, striated longitudinally, stem nodes of the lower part sometimes with fibrous roots, fracture solid. Leaves opposite, mostly crumpled, when whole broadly ovate or cordate, 1–4 cm long, 1–5 cm wide, base slightly concave, margins entire; the upper surface greyish-green or brown, the lower surface pale in colour, midrib distinctly prominent, after soaking in water, the black or brown stripes visible under the light; petioles 1–4 cm long. Some with flowers, yellow, solitary and axillary, long-petioled. Capsules globose. Odour, slight; taste, weak.

Identification Transverse section of stem: Epidermal cells covered with cuticle, glandular hairs sometimes found, with a unicellular head and a 1–2-celled stalk. Cortex broad, sometimes cells containing reddish-brown secretion; secretory canals scattered, surrounded by 5–10 secretory cells, containing reddish-brown lumpy secretion. Endodermis distinct. Pericycle fibres arranged in an interrupted ring, the walls slightly lignified. Phloem narrow. Cambium indistinct. Xylem ringed. Pith usually hollowed. Parenchymatous cells containing starch granules.

Leaf in surface view: Glandular hairs reddish-brown, with a subrounded unicellular head, about 25 µm in diameter, and a unicellular stalk. Secretory canals scattered throughout mesophyll, about 45 µm in diameter, containing reddish-brown secretion. For sparsely pubescent one, non-glandular hair visible on the surface of stems and leaves, 1–17-celled, straight or curved, some cells shrunk, 59–1070 µm long, 13–53 µm in diameter at the base, finely striated on the surface, containing yellowish-brown masses.

Foreign matter Not more than 8% (Appendix IX A).

Processing Eliminate foreign matter, wash briefly, cut into sections and dry in the sun.

Action To remove damp-heat, relieve dysuria, and to promote subsidence of swelling.

Indications Acute urinary infection or urolithiasis with difficult painful urination; jaundice with dark urine, hepatic or biliary calculus; carbuncles, sores, venomous snake bite.

Usage and dosage 15–60 g of the dried herb or 30–120 g of the fresh herb.

Storage Preserve in a dry place.

Herba Plantaginis (车前草, Cheqiancao)

Plantain Herb

Plantain Herb is the dried herb of *Plantago asiatica* L. or *Plantago depressa* Willd. (Fam. Plantaginaceae). The drug is collected in summer, removed from soil, and dried in the sun.

Description *Herb of Plantago asiatica* Roots fascicled, fibrous. Leaves basal, long petioled; lamina crumpled, when whole, ovate-elliptical or broadly ovate, 6–13 cm long, 2.5–8 cm wide; externally greyish-green or blackish-green, with 5–7 distinct arched veins; obtuse or acute at the apex, broadly cuneate at the base, margins entire or irregularly sinuate-dentate. Spikes several, with a long scape. Capsules circumscissile, calyx persistent. Odour, slightly aromatic; taste, slightly bitter.

Herb of Plantago depressa Main roots straight and long. Laminas relatively narrow, long-elliptical or elliptical-lanceolate, 5–14 cm long, 2–3 cm wide.

Identification Lamina in surface view:

Herb of Plantago asiatica The epidermal cells of both surfaces subrectangular, the upper epidermal cells with striated cuticle. Stomata anomocytic, subsidiary cells 3–4. Glandular hairs with an elliptical head of 2 cells, and a unicellular stalk. Non-glandular hairs infrequent, 2–5 celled, 100–320 μ m long, with slightly thickened and faintly warty walls.

Herb of Plantago depressa Non-glandular hair 3–7 celled, 350–900 μ m long.

Total ash Not more than 16.0% (Appendix IX K).

Processing Eliminate foreign matter, wash clean, cut into sections and dry in the sun.

Action To remove heat and to induce diureses, to promote expectoration, to reduce heat in blood and to counteract toxicity.

Indications Edema with oliguria; urinary infection with difficult painful urination; diarrhea caused by summer-damp; cough caused by phlegm-heat; spitting of blood, epistaxis; carbuncles and sores.

Usage and dosage 9–30 g or 30–60 g of the fresh herb to be decocted or to be pounded to obtain the juice for oral administration; for external use, appropriate quantity of the fresh herb to be pounded into paste and applied topically.

Storage Preserve in a ventilated dry place.

Herba Pogostemonis (广藿香, Guanghuoxiang)

Cablin Patchouli Herb

Cablin Patchouli Herb is the dried aerial part of *Pogostemon cablin* (Blanco) Benth. (Fam. Labiatae). The drug is collected when foliage branch glowing luxuriantly, exposed to the sun in day and closed tightly at night repeatedly until comp-

letely dried. According to different habitats, the drug is classified into "Shipai Guanghuoxiang" and "Hainan Guanghuoxiang".

Description Stems somewhat square, frequently branched, branches slightly curved, 30–60 cm long, 2–7 mm in diameter; externally pubescent; texture fragile, easily broken, fracture medullated in the center; old stems subcylindrical, 1–1.2 cm in diameter, covered with greyish-brown cork. Leaves opposite, crumpled into masses, when whole, ovate or elliptical, 4–9 cm long, 3–7 cm wide; greenish white pubescent on both surfaces; apex short-acute or obtuse-rounded, base cuneate or obtuse-rounded, margin irregularly serrate; petioles slender, 2–5 cm long, pubescent. Odour, aromatic, characteristic; taste, slightly bitter.

Shipai Guanghuoxiang Branches relatively thin, externally crumpled, greyish-yellow or greyish-brown, internodes 3–7 cm long, leaf scars large and prominent, covered with cork below the middle part, deeply wrinkled longitudinally, fracture gradually becoming subrounded, pith small. Leaves small and thick, dark greenish-brown or greyish-brown.

Hainan Guanghuoxiang Branches stout, externally even, greyish-brown to pale purplish-brown, internodes 5–13 cm long, leaf scars small and prominent indistinctly, covered with cork near the lower part of branches, shallowly wrinkled longitudinally, fracture obtuse-square. Leaves large and thin, pale brown or pale yellowish-brown.

Identification (1) Powder of the leaf: Pale brown. Epidermal cells irregular, stomata diacytic. Non-glandular hairs 1 to 6-celled, straight or curved at the apex, up to 590 μ m long, walls spinulose, some cells containing yellowish-brown masses. Glandular scales with a unicellular head, frequently window-shaped or cleft in surface view, 37–70 μ m in diameter, and a unicellular, very short stalk. Interceular glandular hairs occurring in the intercellular spaces of the palisade or parenchyma, with a unicellular head, irregularly saccular, 13–15 μ m in diameter, up to about 113 μ m long, and a unicellular, short stalk. Small glandular hairs with a bicellular head and a 1–3-celled, very short stalk. Needle crystals of calcium oxalate minute, scattered in mesophyll cells, up to about 27 μ m long.

(2) Weigh sufficient quantity of the coarse powder, carry out the following tests on the volatile oil obtained as described under determination of volatile oil (Appendix I D).

To 1 drop of the volatile oil add 0.5 ml of chloroform and several drops of 5% solution of bromine in chloroform. Shipai Guanghuoxiang is decolorized at first and then a green colour develops; Hainan Guanghuoxiang is decolorized at first and then a violet colour develops.

To another 1 drop of the volatile oil add 0.5 ml of benzene and small quantity of 5% copper acetate solution, mix well and allow the mixture to stand until separation takes place. Apply the supernatant benzene layer to a slide. After evaporation of the benzene, add 1–2 drops of ethanol to the residue, allow to stand and observe under a microscope. In Shipai Guanghuoxiang numerous greyish-blue needle crystals are visible and in Hainan Guanghuoxiang a small quantity of greyish-blue crystals and green amorphous substance are visible.

(3) Dilute 0.5 ml of the volatile oil obtained from identification test (2), to 5 ml with ethyl acetate, as the test solution. To patchouli alcohol CRS add ethyl acetate to prepare a solution containing 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

$\lambda_R = 700\text{nm}$, measure the integrated value of the absorbance, calculate the content.
It contains not less than 0.04% of astragaloside IV ($C_{41}H_{72}O_{15}$) on the dried basis.

Extractive: Carry out the cold extraction method as described under the determination of water-soluble extractives (Appendix X A), not less than 17.0%.

Processing Radix Astragali Eliminate foreign matter, grade according to size, wash clean, soften thoroughly, cut into thick slices and dry.

Radix Astragali (processed with honey) Stir-frying the slices of Radix Astragali as described under the method for stir-frying with honey (Appendix II D) until no more sticky to fingers.

Action To reinforce *qi* and strengthen the superficial resistance, and to promote the discharge of pus and the growth of new tissue.

Radix Astragali (processed with honey): To reinforce *qi* and invigorate the function of the *spleen*.

Indications Deficiency of *qi* with lack of strength, anorexia and stools, sinking of the *spleen qi* manifested by chronic diarrhea, prolapse of the rectum, hematochezia and abnormal uterine bleeding; spontaneous sweating due to weakened superficial resistance; edema due to deficiency of *qi*; abscess difficult to burst or heal; anemia; diabetes caused by internal heat; albuminuria in chronic nephritis; diabetes mellitus.

Radix Astragali (processed with honey): Deficiency of *qi* with lack of strength, anorexia and loose stools.

Usage and dosage 9~30 g.

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

Radix Aucklandiae

(木香, Muxiang)

Common Aucklandia Root

Common Aucklandia Root is the dried root of *Aucklandia lappa* Decne. (Fam. Compositae). The drug is collected in winter and spring, removed from soil and rootlets, cut into section, and the large one further longitudinally cut into pieces, dried, and removed from the rough outer bark by dashing.

Description Cylindrical or semicylindrical, 5~10 cm long, 0.5~5 cm in diameter. Externally yellowish-brown to greyish-brown, with distinct wrinkles, longitudinal furrows and lateral root scars. Texture hard, uneasily broken, fracture greyish-brown to dark brown, the outer layer greyish-yellow or brownish-yellow, cambium ring brown, having radial lines and scattered brown dotted oil cavities. Odour, characteristic and aromatic; taste, slightly bitter.

Identification (1) Powder: yellowish-green. Inulin more frequent, with radial striations. Xylem fibres mostly in bundles, long fusiform, 16~24 μm in diameter, pit apertures horizontal-porous, crisscross or V-shaped. Reticulate vessels more frequent, bordered pitted vessels present, 30~90 μm in diameter. Fragments of oil cavities visible, containing yellow or brown contents.

(2) Soften the section of the drug with 70% ethanol, then add 1 drop of each of 5% α -naphthol solution and sulfuric

acid; a violet colour is produced.

Total ash Not more than 4.0% (Appendix IX K).

Processing Radix Aucklandiae Eliminate foreign matter, wash clean, soak briefly, soften thoroughly, cut into thick slices, and dry in the shade.

Occurring in subrounded thick slices, 15~30 cm in diameter; externally greyish-brown or brown, the centre marked with chrysanthemum flower-like radial lines and dark brown or greyish-brown annulations at intervals; oil cavities (oil cavities) brown and scattered throughout; the peripheral outer layer yellowish-brown to greyish-brown, wrinkled longitudinally. Texture hard. Odour, characteristic aromatic; taste, bitter.

Radix Aucklandiae (roasted) Spread undried Radix Aucklandiae on paper made of straw and pile up consecutively in style of covering one layer of the drug with one layer of paper in a wired shallow basket, roast on a coke stove or in drying shed until the volatile oil is absorbed by paper, a take out.

Action To relieve pain by promoting the flow of *qi*, and to improve digestion by reinforcing the *spleen* function.
Radix Aucklandiae (roasted): To check diarrhea.

Indications Distending pain in the chest and epigastrium, tenesmus in dysentery; indigestion with anorexia.
Radix Aucklandiae (roasted): Diarrhea with abdominal pain.

Usage and dosage 1.5~6 g.

Storage Preserve in a dry place, protected from moisture.

Radix Bupleuri

(柴胡, Chaihu)

Chinese Thorowax Root

Chinese Thorowax Root is the dried root of *Bupleurum chinense* DC. or *Bupleurum scorzonnerifolius* Willd. (Fam. Umbelliferae). According to the difference of the origin and description, the former known as "Beichaihu" (Northern Chinese Thorowax Root), and the latter is known as "Nanchaihu" (Southern Chinese Thorowax Root). The drug is collected in spring and autumn, removed from the soil, and dried.

Description Beichaihu: Cylindrical or elongated, 6~15 cm long, 0.5~0.8 cm in diameter, root not expanded. Apex remained with 3~15 stem-bases or short fibrous leaf-bases, branched at the lower part. External blackish-brown or light brown, with longitudinal wrinkles, rootlet scars and lenticles. Texture hard and tenacious, easily broken, fracture laminated-fibrous, bark light brown, wood yellowish-white. Odour, slightly aromatic; taste, slightly bitter.

Nanchaihu: Relatively thin, conical. Apex with mucous hairy fibres from withered leaves, usually branched or slightly branched at the lower part. External reddish-brown or blackish-brown, with dense and transverse annulations near the root stock. Texture slightly easily broken, fracture slightly even, non-fibrous. Odour, rancid.

Identification (1) To 0.5 g of the powder add 10 ml water, shake vigorously, a persistent foam is produced.
(2) To 0.5 g of the powder add 20 ml of methanol, heat

Total ash Not more than 10.0% (Appendix X K).

Extractives Carry out the hot extraction method as described under the determination of ethanol-soluble extractives (Appendix X A), use ethanol as the solvent, not less than 15.0%.

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

Action To relieve rheumatic conditions, to remove obstruction of *collaterals*, and to alleviate pain.

Indications Rheumatic or rheumatoid arthralgia with numbness of the limbs, muscle contracture and limitation of motion, fish bone stuck in the throat.

Usage and dosage 6-9 g.

Storage Preserve in a dry place.

Radix Codonopsis

(党参, Dangshen)

Tangshen

Tangshen is the dried root of *Codonopsis pilosula* (Franch.) Nannf., *Codonopsis pilosula* Nannf. var. *modesta* (Nannf.) L. T. Shen or *Codonopsis tangshen* Oliv. (Fam. Campanulaceae). The drug is collected in autumn, washed clean, and dried in the sun.

Description *Root of Codonopsis pilosula* Long cylindrical, slightly curved, 10-34 cm long, 0.4-2 cm in diameter. Externally yellowish-brown to greyish-brown, with numerous warty prominent stem scars and buds on the root stock, and the apex of each stem scar sunkenly dotted; dense transverse annulations occurring below the root stock, gradually sparse downwards, some up to half length of the root while the transverse annulations rare or absent in some cultivars; whole root showing longitudinal wrinkles and scattered transverse lenticles, frequently with blackish-brown gelatinous substances at the fractured area of the rootlets. Texture slightly hard or tenacious, fracture somewhat even, cleft or striated radially, bark pale yellowish-white to pale brown, wood pale yellow. Odour, characteristic and aromatic; taste, sweetish.

Root of Codonopsis pilosula var. *modesta* 10-35 cm long, 0.5-2.5 cm in diameter. Externally yellowish-white to pale yellow, dense transverse annulations occurring below the root stock, frequently up to over half length of the root. Fracture more cleft, bark greyish white to pale yellow, wood light yellow.

Root of Codonopsis tangshen 10-45 cm long, 0.5-2 cm in diameter. Externally greyish yellow to yellowish brown, with distinctly longitudinal wrinkles. Texture slightly soft and compact, fracture less cleft, bark yellowish white, wood pale yellow.

Identification Transverse section: Several up to over ten rows of cork cells, stone cells present at the outer side, single or grouped. Cortex narrow. Phloem broad, often with cracks at the outer side, and with pale yellow laticiferous tube groups scattered throughout and frequently alternated with sieve tubes. Cambium in a ring. Xylem vessels singly scattered or aggregated in groups, arranged radially. Parenchymatous cells containing inulin.

Extractives Carry out the hot extraction method as de-

scribed under the determination of ethanol-soluble extractive (Appendix X A), using 45% ethanol as solvent, not less than 55.0%.

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

Action To reinforce *qi* and invigorate the function of the *spleen* and the *lung*.

Indications Weakness of the *spleen* and the *lung* manifested by shortness of breath, cough, palpitation, anorexia, loose stools; diabetes caused by internal heat.

Usage and dosage 9-30 g.

Precaution Incompatible with *Rhizoma et Radix Veratri*.

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

Radix Curcumae

(郁金, Yujin)

Turmeric Root Tuber

Turmeric Root Tuber is the dried root tuber of *Curcuma wenyujin* Y. H. Chen et C. Ling, *Curcuma longa* L., *Curcuma kwangsiensis* S. G. Lee et C. F. Liang, or *Curcuma phaeocaulis* Val. (Fam. Zingiberaceae). The drugs derived from the former two are known as "Wen Yujin" and "Huang Si Yujin", respectively, and the drugs derived from the others are known as "Gui Yujin" or "Lu Si Yujin", respectively, according to different appearance. The drug is collected in winter when stem and leaves wither, removed from soil and rootlets, steamed or boiled thoroughly, and dried.

Description *Wen Yujin* Oblong or ovoid, slightly compressed or curved, the two ends tapering, 3.5-7 cm long, 1.2-2.5 cm in diameter. Externally pale brown or greyish-brown, with irregular longitudinal wrinkles, the raised longitudinal wrinkles pale in colour. Texture compact, fracture greyish-brown and horny. Endodermis ring distinct. Odour, slightly aromatic; taste, slightly bitter.

Huang Si Yujin Fusiform, sometimes slender at one end, 2.5-4.5 cm long, 1-1.8 cm in diameter. Externally brownish-grey or greyish-yellow, with fine wrinkles. Fracture orange, but edges brownish-yellow to brownish-red. Odour, aromatic; taste, pungent.

Gui Yujin Long conical or oblong, 2-6.5 cm long, 1-1.8 cm in diameter. Externally with sparse and shallow wrinkles or relatively coarse reticulate wrinkles. Odour, slight; taste, slightly pungent, bitter.

Lu Si Yujin Long ellipsoid, rather stout, 1.5-3.5 cm long, 1-1.2 cm in diameter. Odour, slight; taste weak.

Identification Transverse section:

Wen Yujin Epidermal cells sometimes remaining, the outer walls slightly thickened. Velamen narrow, composed of 4-8 layers of cells with slightly sinuous and thin walls, regularly arranged. Cortex 1/2 as wide as the diameter of the root, oil cells poorly visible, endodermis distinct. In stele, phloem bundles and xylem bundles 40-55, respectively, arranged alternatively. Vessels 2-4 in a xylem bundle and xylem fibres slightly lignified, vessels polygonal, thin-walled, 20-90 μ m in diameter. All starch granules in

parenchymatous cells gelatinized.

Huang Si Yujin The walls of the inner most layer of velamen thickened. Sometimes xylem vessels and fibres arranged in a continuous ring, oil cells numerous, pigment cells scattered throughout parenchyma.

Gui Yujin The walls of velamen occasionally thickened, the inner side of velamen showing 1-2 rows of sclerenchymatous cells arranged in a ring, with distinct striations. Vessels subrounded, up to 160 μ m in diameter.

Lü Si Yujin The cells of velamen not thickened. At the outside of stele cortex frequently exhibiting pigment cells. Phloem bundles shrivelled, xylem bundles more, 64-72, vessels flattened.

Water Carry out the determination of water (Appendix IX H, method 2), not more than 15.0%.

Total ash Not more than 9.0% (Appendix IX K).

Processing Wash clean, soften thoroughly, cut into thin slices, and dry; or wash clean, dry, and then break to pieces.

Action To promote the flow of *qi*, to eliminate blood stasis, to calm the nerves and ease the mind, and to increase the flow of bile.

Indications Amenorrhea, dysmenorrhea, distending or pricking pain in the chest and abdomen; impairment of consciousness in febrile diseases, epilepsy, mania; jaundice with dark urine.

Usage and dosage 3-9 g.

Storage Preserve in a dry place, protected from moth.

Radix Cyathulae

(川牛膝, Chuanniuxi)

Medicinal Cyathula Root

Medicinal Cyathula Root is the dried root of *Cyathula officinalis* Kuan (Fam. Amaranthaceae). The drug is collected in autumn and winter, removed from root stock, rootlet and soil, baked or sun-dried to half-dryness, piller¹ up to be softened, and then baked or sunned until dried completely.

Description Subcylindrical, somewhat twisted, slightly tapering downward or less-branched, 30-60 cm long, 0.5-3 cm in diameter. Externally yellowish-brown, with longitudinal wrinkles, rootlet scars and numerous transversely protruding lenticels. Texture tenacious, uneasily broken, fracture pale yellow or brownish-yellow, showing dotted vascular bundles arranged in several concentric circles. Odour, slight; taste sweet.

Identification Transverse section: Cork consisting of several layers of cells. Cortex narrow. Stele large, tertiary vascular bundles collateral, interruptedly arranged in 4-11 whorls, intrafascicular cambium at the inner side visible; vessels singly scattered in xylem, lignified, arranged radially; wood fibres rather developed, sometimes tangentially elongated or arranged in an interrupted ring, vascular system usually separated into 2-9 strands at the central secondary structure, sometimes in the centre of root some sparsely scattered vessel elements visible. Parenchymatous cells containing sand crystals and prisms of calcium oxalate.

Powder: Brown, sand crystals and prisms of calcium ox-

alate scattered or filled in parenchymatous cells. Bordered pitted vessels 10-80 μ m in diameter, pits rounded or elongated transversely, alternative closely arranged, some vessel elements fusiform at the ends. Fibres slit-shaped, curved, tapering into the end, 8-25 μ m in diameter, walls 3-5 μ m thick, pits simple oblique or V-shaped, sometimes showing bordered pits, pit apertures crisscross, pit-canals distinct, dense or sparse.

Extractives Carry out the cold extraction method as described under the determination of water-soluble extractives (Appendix X A), using the granules of the diameter less than 3 mm. Not less than 65.0%.

Processing *Radix Cyathulae* Eliminate foreign matter and root stock, wash clean, soften thoroughly, cut into thin slices, and dry.

In rounded slices, 0.1-0.2 cm thick, 0.5-3 cm in diameter. Externally greyish-yellow, cut surfaces pale yellow or brownish-yellow. Numerous yellow dotted vascular bundles visible.

Radix Cyathulae (stir-fried with wine) Stir-fry slices of *Radix Cyathulae* as described under the method for stir-frying with wine (Appendix II D) to dryness.

Action To eliminate blood stasis and stimulate menstrual discharge, to allay arthralgia and ease the joint, and to relieve urinary disturbance.

Indications Amenorrhea with mass formation in the lower abdomen; detention of the afterbirth; arthralgia with contracture of the muscles and limitation of the legs in motion; hematuria; traumatic injuries.

Usage and dosage 4.5-9 g.

Precaution Contraindicated in pregnancy.

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

Radix Cynanchi Atrati

(白薇, Baiwei)

Blackend Swallowwort Root

Blackend Swallowwort Root is the dried root and rhizome of *Cynanchum atratum* Bge. or *Cynanchum versicolor* Bge. (Fam. Asclepiadaceae). The drug is collected in spring and autumn, washed clean, and dried.

Description Rhizomes thick and short, knotty, mostly tortuous. Some rounded stem scars occurring at the upper part and numerous slender roots fascicled bilaterally at the lower part. Roots 10-25 cm long, 1-2 mm in diameter. Externally brownish-yellow. Texture fragile, easily broken, fracture yellowish-white in bark and yellow in wood. Odour, slight; taste, slightly bitter.

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

Action To remove heat from blood, to relieve dysuria, and to counteract toxicity and cure sores.

Indications Febrile diseases with invasion of the pathogenic factors into the blood; fever due to deficiency of *yin*, in phthisis, or due to deficiency of blood after delivery; acute urinary infection, dysuria with hematuria; carbuncles and other subcutaneous pyogenic infections.

Usage and dosage 4.5-9 g.

Storage Preserve in a ventilated dry place.

pale yellow to yellow in wood showing radial rays, with a pith in the centre. Odourless; taste, slightly bitter.

Identification Transverse section of root: Cork consisting of about 10 or more layers of cells, with rhytidome outside. Cortex consisting of several layers of parenchymatous cells, containing sand crystals of calcium oxalate. Pericycle consisting of fibres and stone cells. Phloem narrow. Cambium in a ring. Xylem well developed, consisting of vessels, tracheids and xylem fibres; rays broad, containing sand crystals of calcium oxalate. Sometimes pith with fibres; parenchymatous cells with pits. Rays of rhizome relatively narrow.

Powder: Brownish-red or brownish-yellow. Cork cells rectangular, brown, containing sand crystals of calcium oxalate. Most fibres scattered singly, 20–25 μm in diameter, walls thickened and lignified, with distinct oblique pits. Spiral and reticulate vessels, 30–50 μm in diameter, the perforated plate of vessel members with numerous rounded pores. Stone cells, oblong, fibrous and branched, 20–50 μm in diameter, thick-walled sometimes observed. Parenchymatous cells in pith subsquare, subrectangular or subrounded, walls slightly thickened, with pits. Parenchymatous cells containing sand crystals of calcium oxalate.

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

Action To arrest perspiration.

Indications Spontaneous sweating, night sweating.

Usage and dosage 3–9 g; for external use, appropriate quantity to be ground into powder and dabbed on the skin.

Storage Preserve in a dry place.

Radix et Rhizoma Rhei

(大黃, Dahuang)

Rhubarb

Rhubarb is the dried root and rhizome of *Rheum palmatum* L., *Rheum tanguticum* Maxim. ex Balf. or *Rheum officinale* Baill. (Fam. Polygonaceae). The drug is collected in late autumn when stem and leaves are withered or in next spring just before budding, removed from rootlet and the outer bark, cut into segment or section, either stringed together to be dried, or dried directly.

Description In subcylindrical, conical, ovoid or irregular-shaped pieces, 3–17 cm long, 3–10 cm in diameter. Externally yellowish-brown to reddish-brown when peeled, sometimes whitish reticulations and scattered star spots (abnormal vascular bundles) visible, occasionally with brownish-black patches of cork, mostly with a hole through which the string passed, and coarse wrinkles. Texture compact, sometimes rather loose and soft in the centre, fracture reddish-brown or yellowish-brown, granular. Pith of the rhizome broad, with star spots arranged in a ring or irregularly scattered. Wood of the root well developed, lined radially, cambium ring distinct, without star spots. Odour, delicately aromatic; taste bitter and slightly astringent, sticky and gritty on chewing.

Identification (1) Transverse section: Most cork and cortex of root removed. In phloem, sieve tube groups distinct. Parenchyma well developed. Cambium in a ring. Xylem

with relatively dense rays, 2–4 cells wide. Containing brown masses; vessels unligified, usually single or several grouped, sparsely arranged. Parenchymatous cells containing clusters of calcium oxalate and abundant starch granules. Pith of rhizome broad, usually showing mucilage cavities, containing reddish-brown masses; abnormal vascular bundles scattered, cambium in a ring, xylem at the outside and phloem at the inside. Rays stellately radiated.

Powder: Yellowish-brown. Clusters of calcium oxalate 20–160 μm , sometimes up to 190 μm in diameter. Bordered-pitted, reticulate, spiral and annular vessels unligified. Starch granules fairly abundant, single granules subspheroidal or polygonal, 3–45 μm in diameter, hilum stellate; compound consisting of 2–8 components.

(2) Sublime a small quantity of the powder, rhombic needles or feathery crystals are visible.

(3) Macerate 0.1 g of the powder in 20 ml of methanol for 1 hour, and filter. Evaporate 5 ml of the filtrate to dryness, dissolve the residue in 10 ml of water, add 1 ml of hydrochloric acid, heat on a water bath for 30 minutes and cool immediately. Extract with 2 quantities, each of 20 ml, of ether, combine the ether extracts, evaporate to dryness and dissolve the residue in 1 ml of chloroform as the test solution. Prepare a solution of Radix et Rhizoma Rhei reference drug in the same manner as the reference drug solution. Dissolve rhein 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 V B), using silica gel H containing sodium carboxymethylcellulose as the coating substance and petroleum ether (30–60°C)-ethyl formate-formic acid (15:5:1) as the mobile phase. Apply separately to the plate 4 μl of each of the three solutions. After developing and removal of the plate, dry it in air, and examine under ultra-violet light (365 nm). The five orange 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 orange fluorescent 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. The spot becomes red under sun-light on exposure to ammonia vapour.

Rhapeticin Macerate warmly 0.2 g of the powder in 2 ml of methanol for 10 minutes, and cool. Apply 10 μl of the supernatant to a piece of filter paper, and develop using 45% ethanol as the mobile phase. After developing and removal of the paper, dry it in air and allow to stand for 10 minutes. Examine under ultra-violet light (365 nm); a persistent bright violet fluorescence is not shown.

Loss on drying When dried at 105°C for 6 hours, loses not more than 15.0% of its weight (Appendix IX G).

Total ash Not more than 10.0% (Appendix IX K).

Acid-insoluble ash Not more than 0.8% (Appendix IX K).

Processing *Radix et Rhizoma Rhei* Eliminate foreign matter, wash clean, soften thoroughly, cut into thick slices or pieces, and dry in the air.

Radix et Rhizoma Rhei (stir-fried with wine) Stir-fry the slices of Radix et Rhizoma Rhei as described under the method for stir-frying with wine (Appendix II D) to dryness.

Radix et Rhizoma Rhei (prepared) Stew or steam the pieces of Radix et Rhizoma Rhei as described under the method for stewing or steaming with wine (Appendix II D) until the drug darkens thoroughly.

Radix et Rhizoma Rhei (carbonized) Stir-fry the slices of

Radix et Rhizoma Rhei as described under the method for carbonizing by stir-frying (Appendix II D) until the outer surface is charred and the inner surface turns to dark brown.

Action To cause catharsis and purge away heat, to reduce heat in blood and counteract toxicity, and to eliminate blood stasis and stimulate menstrual discharge.

Radix et Rhizoma Rhei (stir-fried with wine) To remove toxic heat from the blood in the upper portion of the body.
Radix et Rhizoma Rhei (prepared) To purge away heat and remove toxic substances, but with less cathartic effect.
Radix et Rhizoma Rhei (carbonized) To reduce heat in blood, remove blood stasis, and arrest bleeding.

Indications Fever with constipation, retention of the feces and abdominal pain; dysentery with inadequate discharge from the bowels; jaundice caused by damp-heat; haematemesis, epistaxis, inflammation of eye and swelling of the throat due to heat in the blood; appendicitis with abdominal pain; boils, sores and abscess; amenorrhea due to blood stasis; traumatic injuries; hemorrhage from the upper gastrointestinal tract. External use for scalds and burns.

Radix et Rhizoma Rhei (stir-fried with wine) Inflammation of the eye, swelling of the throat and painful swelling of the gums.

Radix et Rhizoma Rhei (prepared) Boils, sores and abscess.

Radix et Rhizoma Rhei (carbonized) Hemorrhage with blood stasis due to heat in the blood.

Usage and dosage 3–30 g, not to be decocted for a long time if it is used for catharsis; for external use, appropriate quantity to be ground into powder for topical application after mixing with liquid.

Precaution Used with caution in pregnancy.

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

Preparation Rhubarb Liquid Extract.

Radix Euphorbiae Pekinensis (京大戟, Jingdaji)

Peking Euphorbia Root

Peking Euphorbia Root is the dried root of *Euphorbia pekinensis* Rupr. (Fam. Euphorbiaceae). The drug is collected in autumn and winter, washed clean and dried in the sun.

Description Irregularly long conical, slightly curved, usually branched, 10–20 cm long, 1.5–4 cm in diameter. Externally greyish-brown or brown, rough, exhibiting longitudinal wrinkles, transverse lenticels and branch-root scars. Apex slightly expanded, with numerous stem bases and bud scars. Texture hard, uneasily broken, fracture whitish or pale yellow, fibrous. Odour, slight; taste, slightly bitter and astringent.

Identification (1) Powder: Pale yellow. Simple starch granules subspheroid or ovoid, 3–15 μ m in diameter, hilum pointed or slit-shaped; compound granules of 2–3 components. Clusters of calcium oxalate 19–40 μ m in diameter. Bordered pitted and reticulate vessels more commonly found, 26–50 μ m in diameter. Fibres individual or

in bundles, walls relatively thick and non-lignified. Non-articulate laticiferous tubes mostly broken, containing yellow minute latex granules.

(2) To a slice of the drug add 1 drop of each of glacial acetic acid and sulfuric acid, observe under a microscope, a red colour is produced at the laticiferous-tubes of phloem, which gradually disappears within 5 minutes; to another slice, add potassium hydroxide TS, a brownish-yellow colour is produced.

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

Radix Euphorbiae Pekinensis (processed with vinegar) Boil the clean *Radix Euphorbiae* as described under the method of boiling with vinegar (Appendix II D) until vinegar is exhausted. Use 30 kg of vinegar per 100 kg of *Radix Euphorbiae Pekinensis*.

Action To cause drastic purgation.

Indications Anasarca, hydrothorax and ascites with dyspnea, constipation and oliguria.

Usage and dosage 1.5–3 g.

Precaution Contraindicated in pregnancy. Incompatible with *Radix Glycyrrhizae*.

Storage Preserve in a dry place, protected from moth.

Radix Gentianae (龙胆, Longdan)

Chinese Gentian

Chinese Gentian is the dried root and rhizome of *Gentiana manshurica* Kitag., *Gentiana scabra* Bge., *Gentiana triflora* Pall. or *Gentiana ringescens* Franch. (Fam. Gentianaceae). The former three are known as "Longdan" and the later is known as "Jianlongdan". The drug is collected in spring and autumn, washed clean and dried.

Description *Longdan* Rhizomes irregularly lump-shaped, 1–3 cm long, 0.3–1 cm in diameter; externally dark greyish-brown or dark brown, upper part with stem scars or remains of stem bases, surroundings and the lower part bearing numerous slender roots. Roots cylindrical, slightly twisted, 10–20 cm long, 2–5 mm in diameter; externally pale yellow or yellowish-brown, mostly the upper part exhibiting obvious transverse wrinkles, lower part narrower and marked with longitudinal wrinkles and rootlet scars. Texture fragile, easily broken, fracture slightly even, bark yellowish-white or yellowish-brown, wood paler in colour and appearing dotted-ringed. Odour, slight; taste, rather bitter.

Jianlongdan Externally without transverse wrinkles, the outer layer membranaceous, easily falling off, wood yellowish-white, easily separated from bark.

Identification (1) Transverse section:

Longdan Epidermal cells sometimes found, the outer walls relatively thick. Cortex narrow; cells of exodermis subsquare, walls slightly thick, suberized; cells of endodermis elongated tangentially, each cell divided by longitudinal walls into several subsquare small cells. Phloem broad and cleft. Cambium less distinct. Vessels 3–10-grouped. Pith

Precaution Incompatible with Rhizoma et Radix Veratri.

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

Radix Scutellariae (黃芩, Huangqin)

Baical Skullcap Root

Baical Skullcap Root is the dried root of *Scutellaria baicalensis* Georgi (Fam. Labiatae). The drug is collected in spring and autumn, removed from rootlet and soil, dashed to peel the rugged outer bark after being sun-dried, and then dried thoroughly.

Description Conical, twisted, 8–25 cm long, 1–3 cm in diameter. Externally brownish-yellow or dark yellow, bearing sparse warty traces of rootlets, the upper part rough, with twisted longitudinal wrinkles or irregular reticula, the lower part with longitudinal striations and fine wrinkles. Texture hard and fragile, easily broken, fracture yellow, reddish-brown in the centre; the central part of an old root dark brown or brownish-black, withered or hollowed. Odour, slight, taste, bitter.

Identification (1) Powder: Yellow. Phloem fibres scattered singly or in bundles, fusiform, 60–250 µm long, 9–33 µm in diameter, thick-walled, with fine pit-canals. Stone cells subrounded, subsquare or rectangular, relatively thick-walled or heavily thick-walled. Cork cells brownish-yellow, polygonal. Reticulated vessels numerous, 24–72 µm in diameter. Wood fibres frequently broken, about 12 µm in diameter, with oblique pits. Starch granules abundant, simple granules spheroidal, 2–10 µm in diameter, hila distinct, compound granules composed of 2–3 components.

(2) Heat under reflux 2 g of the powder in 20 ml of ethanol for 15 minutes, and filter. To 1 ml of the filtrate add 2–3 drops of lead acetate TS; an orange-yellow precipitate is produced. To another 1 ml of filtrate, add a small quantity of magnesium powder and 3–4 drops of hydrochloric acid; a red colour is produced.

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

Assay Carry out the method for high performance liquid chromatography (Appendix VI D).

Chromatographic system and system suitability Use octadecylsilane bonded silica gel as the stationary phase and methanol-water-phosphoric acid (47:53:0.2) as the mobile phase. The wavelength of the detector is 280 nm. The number of theoretical plates of the column is not less than 2500, calculated with the reference to the peak of baicalin.

Preparation of reference solution Weigh accurately a quantity of baicalin CRS, dried in vacuum at 60°C for 4 hours, dissolve in methanol to produce a solution containing 60 µg per ml as the reference solution.

Preparation of test solution Weigh accurately 0.3 g of medium powder [perform a determination of water (Appendix IX H, method 1)], add 40 ml of 70% ethanol, heat under reflux on a water bath for 3 hours, cool, and filter. Transfer the filtrate to a 100 ml volumetric flask, wash the container and the residue several times with a small volume of 70% ethanol, and filter the washings into the same flask. Dilute with 70% ethanol to volume, and mix well. Accurately measure 1 ml in a 10 ml volumetric flask, dilute with

methanol to volume, and mix well.

Procedures Accurately inject 10 µl of each of the reference solution and the test solution, respectively, into the column, determine and calculate the content. It contains not less than 9.0% of baicalin (C₂₁H₁₈O₁₁) on the dried basis.

Processing *Radix Scutellariae* Eliminate foreign matter, boil for 10 minutes, take out, soften thoroughly, or steam for half an hour, take out, then cut into thin slices and dry, protecting from exposure to strong sunlight. Occurring in subrounded or irregular thin slices; externally yellowish-brown to brown; cut surface yellowish-brown or yellowish-green, striated radially.

Radix Scutellariae (Processed with wine) Stir-fry the slices of *Radix Scutellariae* as described under the method for stir-frying with wine (Appendix II D) to dryness. Occurring in subrounded or irregular thin slices; externally brown; cut surface yellowish-brown, striated radially, showing less burnt patches, sometimes appearing brown in the centre.

Action To remove damp-heat, to quench fire and counteract toxicity, to arrest bleeding, and to prevent abortion.

Indications Discomfort in the chest, nausea and vomiting in epidemic febrile diseases caused by damp-heat or summer-heat; feeling of stuffiness in the abdomen, acute dysentery or jaundice caused by damp-heat; cough due to heat in the lung; high fever with dire thirst; spitting of blood and epistaxis due to heat in blood; carbuncles and sores; threatened abortion.

Usage and dosage 3–9 g.

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

Radix Semiaquilegiae (天葵子, Tiankuizi)

Muskroot-like Semiaquilegia Root

Muskroot-like Semiaquilegia Root is the dried root tuber of *Semiaquilegia adoxoides* (DC.) Makino (Fam. Ranunculaceae). The drug is collected in early summer, washed clean, dried and removed from rootlet.

Description Irregularly short-cylindrical, fusiform, or lump-shaped, somewhat curved, 1–3 cm long, 0.5–1 cm in diameter. Externally dark brown to greyish-black, with irregular longitudinal wrinkles, rootlets or rootlet scars. Apex usually with remains of stems or leaves, covered with several layers of yellowish-brown sheath-like scales. Texture relatively soft, easily broken, fracture whitish in bark and yellowish-white or yellowish-brown and slightly radially striated in wood. Odour slight; taste sweet, slightly bitter and pungent.

Identification (1) Transverse section: Cork consisting of more rows of cells containing brown contents. Cortex relatively narrow, phloem broad, cambium in a ring. Xylem rays up to 20 or more rows of cells wide, vessels arranged radially. Sometimes a small pith visible.

(2) Observe the fracture under an ultra-violet light (365 nm), a yellowish-white fluorescence is shown, which becomes weak on adding acid or alkali.

(3) To 1 g of the powder add 10 ml of 70% ethanol, heat under reflux for 30 minutes, filter. Evaporate the filtrate

PART II
Traditional Chinese Patent
Medicines and Simple
Preparations

Kanlisha

(坎离砂)

Kanli Coarse Powder

Ingredients Radix Angelicae Sinensis 37.5 g; Rhizoma Chuangxiong 50 g; Radix Saposhnikoviae 50 g; Caulis Impatiensis Balsaminae 50 g; Iron chip 10/kg.

Procedure Decoct Radix Angelicae Sinensis, Rhizoma Chuangxiong, Radix Saposhnikoviae and Caulis Impatiensis Balsaminae with a quantity of rice vinegar twice, filter, and combine the filtrates. Calcine iron chips in a furnace to a certain extent, remove out and pour the filtrate on it, stir well, dry in air and sift.

Description A blackish-brown coarse powder; texture heavy, with slightly sour odour of vinegar.

Heating effect Place about 250 g of the drug in a beaker, add 15 ml of 3.5% acetic acid solution and stir well. Pack the mixture into a proper cloth bag, insert a thermometer and set the mercury bulb in the central part of the bag, and tie up the bag closely but air is permeable. Place the bag on a wooden desk and cover with three layers of towel; the temperature in the bag begins to rise after a few minutes and the highest temperature thus reached should not be lower than 75°C.

Action To dispel wind-cold, promote blood circulation and relieve pain.

Indications Rheumatic or rheumatoid arthralgia with numbness of the limbs; epigastric pain with cold sensation.

Usage and dosage Put 250 g of the drug mixed up with 15 g of vinegar (with no excess) into a cloth bag on the afflicted area while it becomes hot, and take it away after cooling. The drug can be used repeatedly for several times, mixed with vinegar for every time by the same procedure. Heat the afflicted part 1-3 times a day.

Specification Each carton cylinder contains 250 g of the powder.

Storage Preserve in well closed containers, protected from moisture.

Kongxian Wan

(控涎丸)

Kongxian Pills

Ingredients Radix Kansui (processed with vinegar) 300 g; Radix Knoxiae 300 g; Semen Sinapis Albae 300 g.

Procedure Pulverize the above three ingredients to fine powder, sift, mix well, make pills with dilute rice paste prepared from 240 g of rice powder or yellow rice powder and water, and dry.

Description Dark brown pasted pills with pale yellow spots on the surface; taste, slightly pungent.

Identification Microscopical: Acondyloes laticiferous tubes occurring in parenchyma. Pigment cells yellowish-brown or reddish-brown, oblong or tubular; needle crystals of calcium oxalate in bundles or scattered. Palisade cells of testa small in surface view, polygonal, with thickened walls; subrectangular in lateral view, the lateral and inner walls

thickened.

Other requirements Comply with the general requirements for pills (Appendix I A).

Action To elimination phlegm and retained fluid.

Indications Accumulation of phlegm fluid in the chest marked by dull chest pain aggravated by cough and difficulty in expectoration; scrofula.

Usage and dosage 1-3 g, 1-2 times a day, to be taken with warm boiled water, date soup or rice soup.

Precaution Contraindicated in pregnancy. Used with caution in weak patients.

Storage Preserve in well closed containers, protected from moisture.

Liangfu Wan

(良附丸)

Liangfu Pills

Ingredients Rhizoma Alpiniae Officinarum 500 g; Rhizoma Cyperi (processed with vinegar) 500 g.

Procedure Pulverize the two ingredients to fine powder, sift and mix well, make pills with water and dry.

Description Brownish-yellow to yellowish-brown watered pills; odour, slightly aromatic; taste, pungent.

Identification Microscopical: Starch granules clavate, reniform or elongated ovoid, 24-44 µm or more in length; hilum pointed, short cleft or trichotomous. Secretory cells subrounded, containing pale yellowish-brown or reddish-brown masses, surrounded by radially arranged cells; fibre bundles reddish brown, 8-10 µm in diameter, walls thickened.

Other requirements Comply with the general requirements for pills (Appendix I A).

Action To warm stomach and regulate the flow of remove qi.

Indications Cold in the stomach combined with stagnation of qi marked by epigastric pain, acid regurgitation, feeling of fullness and distension in the chest and abdomen.

Usage and dosage 3-6 g, 2 times a day.

Storage Preserve in well closed containers, protected from moisture.

Lidan Paishi Pian

(利胆排石片)

Lidan Paishi Tablets

Ingredients Herba Lythymachiae 250 g; Herba Artemisiae Scopariae 250 g; Radix Scutellariae 75 g; Radix Aucklandiae 75 g; Radix Curcumae 75 g; Radix et Rhizoma Rhei 125 g; Semen Arecae 125 g; Fructus Aurantii Immaturus (girdled with bran) 50 g; Natrii Sulfas (purified) 25 g; Cortex Magnoliae Officinalis (processed with ginger) 50 g.

Procedure Pulverize Radix Aucklandiae, Radix et Rhizoma Rhei and Natrii Sulfas to fine powder. Decoct the other ingredients, filter concentrate the decoction to thick extract, add the above powder, mix well, make granules.

compress into 1000 tablets and coat with sugar.

Description Sugar-coated tablets with brown core; taste, bitter and salty.

Identification (1) Microscopical: Clusters of calcium oxalate 60–140 μm in diameter, with obtuse angle. Wood fibres long fusiform, 16–24 μm in diameter, with slightly thickened walls, showing transverse slit-shaped, crossed, V-shaped pit apertures. Observe on mounting in ethanol, irregular crystals almost colourless, with uneven edge, showing slender fissures and granules on the surface.

(2) Grind 5 tablets, removed the sugar coats, add 20 ml of methanol, ultrasonicate for 15 minutes, and filter. Evaporate the filtrate to about 2 ml as the test solution. Prepare a solution of 0.5 g of Radix et Rhizoma Rhei reference drug in 20 ml of methanol in the same manner 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 the upper layer of the mixture of petroleum ether (30–60°C)-ethyl formate-formic acid (15:5:1) as the mobile phase. Apply separately 1 μl of each of the two solutions on the plate. After developing and removal of the plate, dry it in air. Examine under ultra-violet light (365 nm), the five orange-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. Exposure to ammonia vapour, examine under sunlight, the colour of the spots turns to red.

Other requirements Comply with the general requirements for tablets (Appendix I D).

Action To remove damp-heat, increase the flow of bile and expel calculi.

Indications Cholelithiasis, infection of the biliary tract, cholecystitis.

Usage and dosage 6–10 tablets for expelling calculi, 4–6 tablets for treating inflammation, 2 times a day.

Precaution Used with caution in debilitated patients and those with impaired liver function. Contraindicated in pregnancy.

Storage Preserve in tightly closed containers.

Lingbao Huxin Dan

(灵宝护心丹)

Lingbao Huxin Micropills

Lingbao Huxin Micropills are the micropills prepared from Radix Ginseng Rubra, Moschus, Calculus Bovis, Radix Notoginseng and Boneolum Syntheticum etc.

Description Reddish-brown concentrated micropills. Odour, aromatic as Boneolum Syntheticum; taste, bitter, pungent and slightly numb.

Identification (1) Microscopical: Irregular masses pale yellowish-brown, embedded with fine prisms. Clusters of calcium oxalate 20–68 μm in diameter, angle acute.

(2) Pulverize 50 pills to fine powder, add 6 ml of dehydrated ethanol, and continue to grind well and filter. To 1 ml of the filtrate, add 5 drops of glacial acetic acid, 1 ml of 1% furfural and 1 ml of sulfuric acid, the lower layer shows pale red colour, then turn to purple colour, after mixing well, greyish-blue colour is produced.

(3) To 1 ml of the filtrate obtained under Identification test (2) add about 0.3 g of antimony trichloride, 1 ml of chloro-

form, heat, a red colour is produced. Continue to heat, turn to rose-red colour or purple colour.

(4) Pulverize well 0.5 g of the pills to fine powder, add 10 ml of water, transfer to a separator, extract with three quantities, 20, 10 and 10 ml of each, of ether. Combine the ether extracts, evaporate to dryness. Dissolve the residues in 2 ml of ethyl acetate as the test solution. Dissolve 0.5 g of (\pm)-borneol CRS in ethyl acetate to produce a solution containing 3 mg per ml as the reference solution. Carry out the method for thin layer chromatography (Appendix VI B), using silica gel G containing carboxymethylcellulose sodium as the coating substance and petroleum ether (60–90°C)-ethyl acetate (19:2) as the mobile phase. Apply separately to the plate 2–5 μl of each of the two solutions. After developing and removal of the plate, dry it in air. Spray with 5% solution of vanillin in sulfuric acid and visualize under a current of hot air. The spots in the chromatogram obtained with the test solution correspond in position and colour to the spots in the chromatogram obtained with the reference solution.

Weight variation Take 10 pills as one part. Weigh separately to 10 part and calculate the average weight, the variation between the weight of each part and the average weight should not exceed 10%. No more than 2 parts exceed the weight variation limit and none doubles the weight variation limit.

Other requirements Comply with the general requirements for pills (Appendix I A).

Action Strengthen the heart and replenish qi, activating yang and blood circulation, promoting the restoration of consciousness with drugs of fragrant flavour, relieving pain.

Indications Bradycardia, sick sinus syndrome, angina and cardiac insufficiency, arrhythmia.

Usage and dosage 3–4 pills, 3–4 times a day. Taken after meal or follow physician's advice.

Precaution Contraindicated in pregnancy. Few patients sometimes exhibit slight abdominal distension and xerostomia at the first stage of administration, which would naturally disappear after the continued administration, and is not need to stop.

Storage Preserve in tightly closed containers, protected from moisture.

Lingyang Qingfei Wan

(羚羊清肺丸)

Lingyang Qingfei Pills

Ingredients Bulbus Fritillariae Thunbergii 40 g; Cortex Mori (stir-fried with honey) 25 g; Radix Peucedani 25 g; Radix Ophiopogonis 25 g; Radix Asparagi 25 g; Radix Trichosanthis 50 g; Radix Rehmanniae 50 g; Radix Scrophulariae 50 g; Herba Dendrobii 100 g; Radix Platycodi 50 g; Folium Eriobotryae (stir-fried with honey) 50 g; Semen Armeniacae Amarum (stir-fried) 25 g; Radix Tinosporae 25 g; Flos Lonicerae 50 g; Folium Isatidis 25 g; Fructus Gardeniae 50 g; Radix Scutellariae 25 g; Radix Isatidis 25 g; Cortex Moutan 25 g; Herba Menthae 25 g; Radix Glycyrrhizae 15 g; Radix et Rhizoma Rhei (Prepared) 25 g; Pericarpium Citri Reticulatae 30 g; Pulvis Cornus Saigae Tataricae 6 g.

Procedure Pulverize the above twenty three ingredients, except Pulvis Cornus Saigae Tataricae, to fine powder, sift. Triturate Pulvis Cornus Saigae Tataricae with the above

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In America, Africa, and India the drug is used as an abortive and as an emmenagogue.

In Indonesia, cumin is used in cases of bloody diarrhea, headache (paste is applied to the forehead), and is taken orally for rheumatic ailments.

PRECAUTIONS AND ADVERSE REACTIONS

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

DOSAGE

Mode of Administration: Cumin is used both internally and externally in ground form and as a pressed oil.

Daily Dosage: The average single dose is 300 to 600 gm (5 to 10 fruits) of drug.

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Cumin

See *Cuminum Cyminum*

Cup Plant

See *Silphium Perfoliatum*

Cupmoss

See *Cladonia Pyxidata*

Cupressus Sempervirens

Cypress

DESCRIPTION

Medicinal Parts: The medicinal parts are the cones, branches, and the oil.

Leaves, Stem and Root: *Cupressus sempervirens* is a tree which grows up to 30 m tall. The leaves are 0.5 to 1 mm, dark green, and obtuse. The male cones are 4 to 8 mm, the female, 25 to 40 mm. They are elliptical-oblong (rarely, globose), green when young and shining yellowish-gray when ripe, with 8 to 14 short and obtusely spiked scales. There are 8 to 20 seeds on each scale.

Habitat: The plant is indigenous to Turkey and is cultivated throughout the Mediterranean region.

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Chief components: alpha-pinenes, D-camphene, D-silvestren, p-cymene, L-cadinenes, cedrol, terpinenol-4, terpineol, acetyl- and isovalerianyl monoterpene ester

EFFECTS

Cypress acts as an expectorant.

INDICATIONS AND USAGE

The drug is used externally for head colds, coughs, and bronchitis.

PRECAUTIONS AND ADVERSE REACTIONS

Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded. Kidney irritation is likely with intake of larger dosages.

DOSAGE

Mode of Administration: Occasionally, Cypress is used externally as an ointment.

LITERATURE

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Curcuma Domestica

Turmeric

DESCRIPTION

Medicinal Parts: The medicinal parts are the stewed and dried rhizome.

Flower and Fruit: The inflorescence is cone-like, 10 to 15 cm long, and is attached to a stem enclosed in a sheathing petiole. The flower has 2 pale green bracts, which are 5 to 6 cm long. The covering bracts are whitish, often red-tinged. The individual flowers are yellowish white or yellow. The flowers have a tubular, 3-lobed calyx and funnel-shaped, 3-tipped corolla. The fruit is a globular capsule.

Leaves, Stem and Root: *Curcuma domestica* is a perennial, erect, and leafy plant with very large, lily-like leaves up to 1.2 m long. The leaf blade is ovate-lanceolate, thin, entire-

marginated, and narrows to a long sheath-like petiole. The main rhizome is thickened to a tuber and has numerous roots. The roots in turn terminate in partially elliptical tubers. The secondary rhizomes are digit-shaped with no roots. All rhizomes are yellowish-brown with stipules and appear transversely ringed when they die.

Habitat: Probably indigenous to India. Cultivated today in India and other tropical regions of southern Asia.

Production: Turmeric root consists of the finger-like, often tuber-like, scalded and dried rhizomes of *Curcuma longa*. The plant is harvested at the end of the growing season and sun dried.

Not To Be Confused With: *Curcuma xanthorrhiza*

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Volatile oil: chief components alpha- and beta-turmerone, ar-turmerone, alpha- and gamma- atlantone, curlone, zingiberene, curcumenol

Curcuminoids: including curcumin, demethoxycurcumin, bidemethoxycurcumin

1,5-diaryl-penta-1,4-dien-3-on- derivatives

Starch

EFFECTS

Turmeric has choleric, cholikinetic, antihepatotoxic, anti-hyperlipidemic and anti-inflammatory. It is also antioxidative, antitumoral and antimicrobial. It has insect repellent and antifertile effects. It also effects prostaglandin.

INDICATIONS AND USAGE

- Liver and gallbladder complaints
- Loss of appetite

Turmeric is used for dyspeptic disorders, particularly feelings of fullness after meals and regular meteorism. In folk medicine, the drug is used for diarrhea, intermittent fever, dropsy, bronchitis, colds, worms, leprosy, kidney inflammation and cystitis. Other uses include, headaches, flatulence, upper abdominal pains, chest infections, fever, diarrhea, colic, amenorrhea, and blood rushes. It is used externally for bruising, leech bites, festering eye infections, inflammation of the oral mucosa, inflammatory skin conditions, and infected wounds.

Efficacy of the folk indications are not proven.

PRECAUTIONS AND ADVERSE REACTIONS

Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded. Stomach complaints can occur following extended use or in the case of overdose.

DOSAGE

Mode of Administration: Comminuted drug, as well as other galenic preparations for internal use.

Preparation: To prepare an infusion, scald 0.5 to 1 gm with boiling water, cover and draw for 5 minutes and then strain. The tincture strength is 1:10.

Daily Dosage: The average daily dose of the drug is 1.5 to 3 gm of powder, 2 to 3 times daily between meals. The infusion dose is 2 to 3 cups between mealtimes. The tincture dose is 10 to 15 drops 2 to 3 times daily.

Storage: Turmeric should be protected from light.

LITERATURE

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Curcuma Xanthorrhizia

Curcuma

DESCRIPTION

Medicinal Parts: The medicinal parts are the dried, tuberous rhizomes cut into slices.

Flower and Fruit: The inflorescence is large, purple or crimson. The corolla has a red margin. Otherwise it is very similar to *Curcuma domestica*.

Leaves, Stem and Root: The plant is a perennial, 1.75 m high and leafy. The leaves are in long thin sheaths on the rhizome. The leaf blades are broadly lanceolate or oblong and have a narrow, purple mark on the midrib. The main rhizome is thickened like a tuber, ovate, the size of a fist with numerous roots and thin lateral rhizomes. The roots terminate partially in ovate tubers.

Habitat: Indigenous to the forests of Indonesia and the Malaysian peninsula. Cultivated mainly on Java, in Malaysia, Thailand and the Philippines.

Production: Curcuma is cultivated and harvested in the second year of growth. After the rhizome has been washed, the main thick root is isolated, cut and dried at a temperature of 50°C.

Not To Be Confused With: The rhizome of *Curcuma domestica*

Other Names: Tewon Lawa, Temu Lawak

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Volatile oil: chief components ar-curcumene (alpha-curcumene), xanthorrhizol, beta-curcumene, germacrene, furanodien, furanodienone

Curcuminoids: including curcumin, demethoxycurcumin

Non-phenolic diarylheptanoids

Starch

EFFECTS

Curcuma acts in a similar manner to turmeric root but is mainly choleric and antitumoral (animal testing).

INDICATIONS AND USAGE

- Liver and gallbladder complaints
- Loss of appetite

Curcuma is used for dyspepsia, particularly feelings of fullness after meals and meteorism.

In Indian folk medicine, it has long been used for liver and gallbladder complaints.

PRECAUTIONS AND ADVERSE REACTIONS

Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded. Stomach complaints can occur following extended use or in the case of overdose. Because of the stimulating effect of the drug upon the biliary tract, it should not be administered if there is a bile duct blockage. Colic can occur when the patient suffers from gallstones.

DOSAGE

Mode of Administration: Commuted drug for infusions and other galenic forms for internal use.

Preparation: The infusion is prepared by pouring 1 cup of boiling water over 1/2 tsp of drug and straining after 10 minutes.

Daily Dosage: The average daily dose is 2 gm of drug; Infusion: 2 to 3 times daily between meals.

Storage: It should be protected from light.

LITERATURE

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Lysimachia Nummularia

Moneywort

DESCRIPTION

Medicinal Parts: The medicinal parts are the fresh or dried whole flowering plant.

Fruit and Flower: The flowers are solitary or in pairs. The leaf axils have 5 free, almost cordate sepals. The corolla is rotate, divided into 5 and fused at the base. It is rich yellow and spotted with dark red glands on the inside. There are 5 glandular-haired stamens fused at the base and 1 ovary. The fruit is a 4 to 5 mm long globular capsule. The seeds are triangular, blackish-brown, warty and 1.5 mm long.

Leaves, Stem and Root: The plant is a perennial. The stem is a runner-like creeper, is lightly branched, quadrangular, glabrous to slightly pubescent and roots at the nodes. It grows from 10 to 45 cm. The leaves are entire-margined, crossed-opposite, short-petioled, red-glandular punctate and orbicular elliptical.

Habitat: The plant is indigenous to all of Europe and the Caucasus and has been introduced into America and Japan.

Production: Moneywort is the aerial part of *Lysimachia nummularia*. The whole flowering plant, including the root, is collected, cleaned, and dried in the sun.

Other Names: Creeping Jenny, Creeping Joan, Herb Twopence, Meadow Runagates, Running Jenny, Serpentaria, String of Sovereigns, Twopenny Grass, Wandering Jenny, Wandering Tailor

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Flavonoids: including, among others, glycosides of myricetins, kaempferols and quercetins, including, among others, rutin, hyperosides

Tannins

Triterpene saponins

The constituents of the drug have not been fully investigated.

EFFECTS

Moneywort is mildly astringent and expectorant. Extracts of the aerial plant parts are said to be antibacterial in vitro, however, scientific results are not available.

INDICATIONS AND USAGE

It is a constituent of gels, ointments and drops for dermatological preparations. Moneywort is used externally as a vulnerary and for acute and chronic eczema. It is used internally for diarrhea, to increase salivation, and as an expectorant for coughs.

PRECAUTIONS AND ADVERSE REACTIONS

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

DOSAGE

Preparation: To make a tea, pour 250 ml boiling water over 2 heaping teaspoonfuls drug and leave to draw for 5 minutes.

Daily Dosage: For the treatment of coughs, drink 1 cup of tea, 2 to 3 times daily with honey if desired.

LITERATURE

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Lysimachia Vulgaris

Loosestrife

DESCRIPTION

Medicinal Parts: The medicinal part is the dried herb.

Flower and Fruit: The flowers grow in long peduncled racemes in the axils of the upper stem and in terminal paniced inflorescences. The pedicle is about 1 cm long, downy, and glandular-haired. The calyx is split almost to the base. The filaments are glandular-haired, usually fused to the middle with each other and in a tube containing the ovary. The seeds are triangular, covered thickly in long warts, whitish, and 1.5 mm long.

Leaves, Stem and Root: The plant is a perennial and has underground runners, which produce new buds. The stem is erect, up to 1.5 m tall, branched, obtusely angular, leafy and thickly downy. The leaves are slightly downy with glandular hairs. The leaves are in whorls or opposite, rarely spiralled, up to 14 cm long and 3.5 cm wide, short-petioled, tightly reticulate and red-glandular punctate.

Habitat: The plant is found in the temperate regions of Europe and Asia.

Other Names: Yellow Willowherb

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Flavonoids: glycosides of the myricetin, kaempferol and quercetin, including among others rutin

The constituents of the drug have not been extensively investigated.

EFFECTS

Loosestrife has an astringent effect. The main active principle is rutin.

INDICATIONS AND USAGE

Loosestrife is used for scurvy, diarrhea and dysentery as well as hemorrhages (nose bleeds and heavy menstrual blood flow) and wounds.

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 herb is used externally in the powdered form.

LITERATURE

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Lythrum Salicaria

Purple Loosestrife

DESCRIPTION

Medicinal Parts: The medicinal parts are the flowering plant without the roots and flowering branch tips.

Flower and Fruit: The purple flowers are in axillary whorls and form terminal spikes. There are 6 small sepals, 6 long thin tips, 6 free petals, 12 stamens, and 1 half-superior ovary. There are flowers with long, short, or medium-long styles, and similar stamens.

Leaves, Stem and Root: The plant is an annual and grows from 60 to 120 cm high. It has a creeping rhizome with 4 to 6 unbranched, erect, 6-sided, and reddish brown pubescent stems. The leaves are simple lanceolate 7.5 to 15 cm long, sometimes opposite and sometimes clasping whorls.

Habitat: The plant is indigenous to Europe including Russia, Central Asia, Australia, and North America.

Production: The flowering plants, before the seeds form, are cut and gathered during the blossoming period, which occurs from June to August. The material is bound into small bundles. It is hung in an open-air, shaded area to dry.

Other Names: Loosestrife, Lythrum, Purple Willow-herb, Long Purples, Milk Willow-herb, Rainbow Weed, Soldiers, Spiked Loosestrife, Spiked, Willow Sage, Salicair, Flowering Sally, Blooming Sally

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Tannins (ellagitannins = lythartannin, condensed tannins)

Flavonoids: including, among others, vitexin, orientin

Phthalides: diisobutyl-, butyl-, isobutyl-, dibutylphthalides

EFFECTS

The active agents are tannin, pectin, resins, cholin, and salicarin.

The drug has an anti-inflammatory, astringent, and antibiotic effect. The astringent properties of the Purple Loosestrife is attributed to not just the tannin content, but also to the glycoside salcarin, which has a special antimicrobial effect on various bacteria in the intestinal tract.

INDICATIONS AND USAGE

The drug is used internally for diarrhea, chronic intestinal catarrh, and menstrual complaints; externally, in the treatment of varicose veins, bleeding of the gums, hemorrhoids, and eczema.

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 as well as externally.

Preparation: For internal use, an infusion is made from 3 gm of the drug added to 100 ml of water. To prepare a tincture, add 20 gm of the drug to 100 ml of 20% alcohol (leave to set for 5 days).

Daily Dosage: Two to 3 cups of an infusion are to be taken per day. Two to 3 teaspoons of the tincture should be taken per day.

Storage: Keep wrapped in paper or in cloth sacks.

LITERATURE

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Madder

See *Rubia Tinctorum*

Magnolia Glauca

Magnolia

DESCRIPTION

Medicinal Parts: The bark is the medicinal part.

Leaves, Stem and Root: The inner bark occurs in long, fibrous strips. The outer surface is rough, almost granular and pitted. The inner surface is striated but almost smooth. The fracture is short with the inner part tough and fibrous.

Habitat: The plant is indigenous to North America.

Other Names: White Laurel, Beaver Tree, Swamp Sassafras, White Bay, Sweet Bay, Holly Bay, Indian Bark, Red Bay, Swamp Laurel

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Neolignans: magnolol

The constituents of the drug have not been widely investigated.

EFFECTS

Magnolia has diaphoretic, anti-inflammatory, and stimulant effects. It is also a tonic.

INDICATIONS AND USAGE

The preparations are used for digestive disorders; used rarely, except in oriental medicine.

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: Magnolia has been used internally as a powder or liquid extract.

LITERATURE

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Mahonia Aquifolium

Mountain Grape

DESCRIPTION

Medicinal Parts: The medicinal parts are the dried rhizome and the roots, the dried branch and twig bark as well as the root bark.

Flower and Fruit: The heavily scented flowers are either in dense 5 to 8 cm panicles or in twos or threes in erect 5 to 8 cm racemes in the leaf axils. The flowers are yellow and have 9 sepals, 6 petals and 6 stamens, which are about 8 cm long. The pedicles are 5 to 10 mm long. The fruit is a globose, purple-blue, frosted berry with red juice. The 2 to 5 seeds are glossy brown.

Leaves, Stem and Root: The plant is a fast-growing, evergreen, stoloniferous shrub about 50 to 150 cm high with stout stems, sparingly branched. The leaves are odd-pinnate, 10 to 20 cm long with 3 to 6 pairs of leaflets. The leaflets are 4 to 8 by 2 to 4 cm, ovate, distally spinose dentate, coriaceous, dark and shining green.

Habitat: Indigenous to the pacific U.S.; ornamental or cultivated in Europe.

Production: Mountain Grape bark consists of the branch and twig bark as well as the twig tips of Mahonia aquifolium.

Other Names: Holly-leaved Berberis

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Isoquinoline alkaloids (2.4-4.5%) of the- benzyl isoquinoline type: including among others berberine- bisbenzylisoquinoline-type: including among others berbamine, oxyacanthine- aporphine-type: including among others isocorydin

EFFECTS

The plant has an antiproliferic effect caused by the alkaloid content, special Barberry (Berberin). It is an antipsoriatic when used externally.

INDICATIONS AND USAGE

In homeopathy for dry skin rashes (for dandruff between the acute phases) and in the treatment of psoriasis.

in isolated cases (rhinitis, conjunctivitis, asthma, urticaria). Incorrect administration procedures (with too little fluid) can lead to obstruction (blockage) of the esophagus or of the intestine, particularly with older people.

Drug Interactions: Absorption of other drugs taken simultaneously could be delayed.

DOSEAGE

Mode of Administration: Whole or ground seeds and other galenic preparations for oral application.

Preparation: Available in standardized preparations from the U.S. and France.

Daily Dose: The recommended daily dose is 10 to 30 g drug. Observe ample intake of liquid. As a laxative, 10 g drug soaked in 100 ml water, to be followed by at least 200 ml of water (1 teaspoonful = 4.7 g drug).

LITERATURE

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Plantago Isphagula

Psyllium

DESCRIPTION

Medicinal Parts: The medicinal part is the ripe seed.

Flower and Fruit: The flowers are on cylindrical, glabrous or finely pubescent scapes, which are only slightly longer than the leaves. They form 0.5 to 3.5 cm long spikes. The bracts are about 3 mm, suborbicular to ovate and sometimes shortly pubescent. The sepals are about 2.5 mm, similarly shaped, almost free, keeled at the apex with wide scarious margins. The anterior ones are usually pubescent. The corolla-tube is 1.5 to 2 mm long and glabrous. The lobes are 2.5 mm, ovate-orbicular, subobtusate to very shortly acuminate. The stamens are exerted up to 1 mm and the capsule is about 3 mm. The seeds are 2.2 to 2.5 mm and cymbiform.

Leaves, Stem and Root: The plant is an annual almost stemless, softly pubescent plant with one or several rosettes. The leaves are 2.5 to 12 cm by 0.1 to 0.8 cm, linear to linear-lanceolate, entire-margined or slightly denticulate and sparsely to densely villous-lanate.

Habitat: The plant grows in India, Afghanistan, Iran, Israel, northern Africa, Spain and the Canary Islands. It is cultivated in India and neighboring countries, Arizona and southern Brazil.

Production: Psyllium consists of the ripe seeds or epidermis of *Plantago ovata* (synonym: *Plantago isphagula*).

Other Names: Indian Plantago, Ispaghula, Sand Plantain, Spigel

ACTIONS AND PHARMACOLOGY

COMPOUNDS: PLANTAGINIS OVATAE SEMEN

Mucilages (20-30%, parent substances arabinoxylans)

Fatty oil

Iridoide monoterpenes: aucubin

EFFECTS: PLANTAGINIS OVATAE SEMEN

When used for diarrhea, psyllium increases the passage time of the bowel content through bonding of water. When used for constipation, it decreases the passage time of the bowel content through increase in the volume of the stool. It also lowers serum-cholesterol levels.

COMPOUNDS: PLANTAGINIS OVATAE TESTA

Mucilages (parent substances arabinoxylans)

EFFECTS: PLANTAGINIS OVATAE TESTA

When used for diarrhea, psyllium increases the passage time of the bowel content through bonding of water. When used for constipation, it decreases the passage time of the bowel content through increase in the volume of the stool. It also

lowers serum-cholesterol levels. Psyllium also reduces postprandial blood sugar elevation.

INDICATIONS AND USAGE

PLANTAGINIS OVATAE SEMEN AND TESTA

- Constipation
- Diarrhea
- Raised levels of cholesterol

Psyllium is used for habitual constipation and disorders where easy bowel movements with a loose stool is desirable (e.g., in patients with anal fissures and hemorrhoids; following anal/rectal surgery; and during pregnancy) and as a secondary medication in the treatment of various kinds of diarrhea and in the treatment of irritable bowel.

CONTRAINDICATIONS

PLANTAGINIS OVATAE SEMEN AND TESTA

The drug is contraindicated in patients who have pathological narrowing in the gastrointestinal tract, obstruction or threatening obstruction of the bowel (ileus), or difficulties in regulating diabetes mellitus.

PRECAUTIONS AND ADVERSE REACTIONS

PLANTAGINIS OVATAE SEMEN AND TESTA

General: No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages. Allergic reactions could however arise in isolated cases (rhinitis, conjunctivitis, asthma, urticaria). Incorrect administration procedures (with too little fluid) can lead to obstruction of the esophagus or of the intestine, particularly with older people.

Drug Interactions: The absorption of other drugs taken simultaneously may be delayed. There is a possibility that insulin dosage adjustment (downward) will be necessary when diabetics use psyllium products.

DOSAGE

PLANTAGINIS OVATAE SEMEN

Mode of Administration: The whole or coarsely-chopped drug as well as other galenic preparations are used internally. Sufficient fluid must be taken with the drug (150 ml water per 5 gm drug). The dose should be taken one-half hour to one hour after taking other medication.

Daily Dosage: The daily dosage ranges from 12 to 40 gm of the drug. Unless otherwise prescribed, 1 to 3 teaspoonfuls (5 to 15 gm drug) should be soaked in a little water, and taken in the mornings and evenings with sufficient liquid (1 to 2 glasses).

PLANTAGINIS OVATAE TESTA

Mode of Administration: The whole drug as well as other galenic preparations are taken orally.

Daily Dosage: The daily dosage is 4 to 20 gm of the drug prepared accordingly. Ample intake of liquid should be ensured (150 ml of water per 5 gm drug).

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PLANTAGINIS OVATAE TESTA

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Plantago Lanceolata

Plantain

DESCRIPTION

Medicinal Parts: The medicinal parts are the dried leaves, the dried herb and the fresh plant.

Flower and Fruit: The globular or shortly cylindrical spikes are on erect or ascending, 5-grooved, appressed pubescent peduncles. The flowers are small, almost colorless behind scarious, narrow-acuminate bracts. The scarious calyx is deeply divided into 4 parts and has a cylindrical tube and a margin with 4 ovate tips. There are 4 long stamens with yellowish-white filaments and anthers and 1 superior ovary. The fruit is a bivalvular, 3 to 4 mm long capsule. The seeds are oblong, 2 mm long and blackish.

Leaves, Stem and Root: The plant is perennial and grows from 5 to 50 cm high. It has a very fibrous root. All the leaves are in basal rosettes and are lanceolate or linear lanceolate, deeply 3 to 5 ribbed, entire-margined or short-dentate.

Habitat: The plant is widespread in the cool temperate regions of the world.

Production: Plantain herb consists of the fresh or dried above-ground parts of Plantago lanceolata, harvested at flowering season.

Not To Be Confused With: The similar Digitalis-lanata leaves.

Other Names: Buckhorn, Chimney-sweeps, Headsman, Rib-grass, Ribwort, Ripplegrass, Soldier's Herb

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Iridoide monoterpenes (2-3%): chief components are aucubin (rhinanthin) and catalpol

Mucilages: (2-6%, glucomannans, arabinogalactane, rhamnogalacturonane)

Flavonoids: including among other chief components apigenine-6,8-diglucoside, luteolin-7-glucuronide

Caffeic acid esters: chlorogenic acid, neochlorogenic acid, acteoside (verbascoside)

Tannins

Hydroxycoumarins: aesculetin

Saponins (traces)

Silicic acid

can be increased by simultaneous application of thiazide diuretics, corticoadrenal steroids, and liquorice root.

Pregnancy: Use during pregnancy or while nursing only after consulting a physician.

Pediatric Use: The drug is not to be administered to children under 12 years of age.

DOSAGE

Mode of Administration: Liquid or solid forms of medication are exclusively for oral use. The drug is used as comminuted drug, powder or dry extracts for infusions, decoction, and as a cold maceration or elixir.

Preparation: To prepare an infusion, add 2 gm finely cut drug to boiling water and strain after 10 minutes. (1 teaspoonful = 2.5 gm drug)

Daily Dosage: 20 to 30 mg hydroxyanthracene derivatives daily, calculated as cascarioside A.

The individually correct dosage is the smallest dosage necessary to maintain a soft stool.

Stimulating laxatives must not be used over an extended period of time (1-2 weeks) without medical advice.

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Rhatany

See *Krameria Triandra*

Rheum Palmatum

Rhubarb

DESCRIPTION

Medicinal Parts: The medicinal parts are the dried underground parts and the underground parts freed from the stem remains, smaller roots and most of the root bark in the dried form. Garden Rhubarb is *Rheum ponticum*.

Flower and Fruit: The inflorescence is an erect panicle foliated to the tip. The flowers consist of narrow, red, pink or whitish yellow tepals, which are curved and located far back in the mature flowers to facilitate wind pollination. The fruit is red-brown to brown, and oval. The fruit is angular, about 10.2 mm to 7.8 mm wide and usually has scarious wings. The nutlet is 6 to 10 mm long and 7 mm in diameter.

Leaves, Stem and Root: The plant is a large, sturdy herbaceous perennial. The stem grows to over 1.5 m high. The leaves are orbicular-cordate, palmate lobed, somewhat rough on the upper surface or smooth and 3 to 5 ribbed. The lobes are oblong-ovate to lanceolate, dentate or pinnatisect. The root system consists of a tuber, which after a number of years measures 10 to 15 cm in diameter and has arm-thick lateral roots.

Habitat: The plant is indigenous to the western and north-western provinces of China and is cultivated in many regions around the world. The main producers are China and Russia.

Production: Rhubarb consists of the dried underground parts of *Rheum palmatum*, *Rheum officinale* or of both species. Stem parts, roots and most of the bark are removed from the rhizomes.

Not To Be Confused With: Other *Rheum* species such as *Rheum raphaniticum* or *Rheum rhabarbarum*.

ACTIONS AND PHARMACOLOGY

COMPOUNDS

Anthracene derivatives (3-12%): chief components 1- or 8 β -glucosides of the aglycones rheumemodin, aloec-emodin, rhein, chrysophanol, physcion (together 60-80%), 8,8'-diglucosides of dianthrone (10-25%), including, among others, sennosides A and B

Tannins: gallo tannins, including, among others, galloylglucose, galloylsaccharose, lindleyine, isolindleyine

Flavonoids (2-3%)

Naphthohydroquinone glycosides

EFFECTS

The main effect is laxative, primarily due to the influence of the herb on the motility of the colon, inhibiting stationary and stimulating propulsive contractions. This results in an accelerated intestinal passage and because of the active chloride secretion, increases water and electrolyte content of stool.

INDICATIONS AND USAGE

■ Constipation

Constipation, bowel movement relief with anal fissures, hemorrhoids, and after recto-anal surgery and in preparation for diagnostic interventions of the gastrointestinal tract.

CONTRAINDICATIONS

Rhubarb is contraindicated in cases of intestinal obturation, acute inflammatory intestinal disease, appendicitis and abdominal pain of unknown origin.

PRECAUTIONS AND ADVERSE REACTIONS

General: Spasmodic gastrointestinal complaints can occur as a side effect to the drug's purgative effect. Long-term use leads to losses of electrolytes, in particular K(+) ions, and as a result of this to hyperaldosteronism, inhibition of intestinal motility and enhancement of the effect of cardioactive steroids; in rare cases also to heart arrhythmias, nephropathies, edemas and accelerated bone deterioration.

The question of the increase in probability of the appearance of carcinomas in the colon following long-term administration of anthracene drugs has not yet been fully clarified.

Recent studies show no connections between the administration of anthracene drugs and the frequency of carcinomas in the colon.

Drug Interactions: Potassium deficiency can cause an increase in the effect of cardioglycosides.

Pregnancy: Use during pregnancy or while nursing only after consulting a physician.

Pediatric Use: The drug is not to be administered to children under 12 years of age.

DOSAGE

Mode of Administration: Liquid or solid forms of medication are exclusively for oral use. The drug is available as comminuted drug, powder or dry extracts for teas, decoctions, cold macerations or elixirs. Extracts of the drug are often constituents of laxatives, chologogics and gastrointestinal remedies, and are found in "slimming cures", "spring-time tonics" and "blood purifying" teas.

Preparation: To prepare an infusion to be used as a laxative, use 1.0-2.0 gm coarse powdered drug; for a stomachic, 0.1 to 0.2 gm powdered drug stirred with sufficient liquid (may be flavored with cinnamon, ginger, or peppermint oil) or scald and strain after 5 minutes. (1 teaspoonful = approximately 2.5 gm drug)

Daily Dosage: As a laxative, the dose is 1.0 to 2.0 gm of drug prepared according to instructions above. As an astringent and stomachic, the dose is 0.1-0.2 gm.

1.2 to 4.8 gm drug corresponds to 30 to 120 mg hydroxyanthracene derivatives/day, calculated as rhein. Stimulating laxatives must not be used over an extended period (1 to 2 weeks) without medical advice.

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Rhododendron Ferrugineum

Rust-Red Rhododendron

DESCRIPTION

Medicinal Parts: The medicinal parts are dried foliage leaves, the dried leafy branches, and the fresh leafy branches.

Flower and Fruit: The pink flowers are in umbel-like racemes. The calyx has 5 short ovate tips. The corolla is fused and funnel-shaped with an edge divided into 5

segments. It is covered on the outside with golden yellow resin spots. There are 10 stamens and 1 superior ovary. The fruit is a 5-valved capsule. The seeds are fusiform, about 1 mm long and light brown.

Leaves, Stem and Root: The plant is an evergreen shrub up to 1 m high and is richly branched from the base upwards. The branches are sturdy and elastic with gray-brown bark. The leaves are oblong-lanceolate, tough and glabrous. The margin is entire, involuted. The leaves are dark green above, densely scaled underneath and sometimes rust-colored.

Characteristics: The leaves are not ciliate at the edge.

Habitat: The plant grows in the alpine chain from the Pyrenees to the southern Croatian mountains but not in the Carpathians.

Production: Rust-Red Rhododendron consists of the dried leaves of Rhododendron ferrugineum.

Not To Be Confused With: The leaves of *R. hirsutum*. The plant product may be altered through the addition of cranberry leaves.

Other Names: Rosebay, Snow Rose

ACTIONS AND PHARMACOLOGY

COMPOUNDS: RHODODENDRON AUREUM

Diterpenes of the andromedan-type (presence questionable)

Hydroquinone glycosides: arbutin

Phenyl butane derivatives: rhododendrol and its bitter glucoside rhododendrine (betuloside)-flavonoids

COMPOUNDS: RHODODENDRON FERRUGINEUM

Diterpenes of the andromedan-type (presence questionable, but probable)

Phenyl butane derivatives: rhododendrol and its bitter glucoside rhododendrine (betuloside)-flavonoids

COMPOUNDS: RHODODENDRON PONTICUM

Diterpenes of the andromedan-type: grayanotoxin I (andromedotoxin, acetyl andromedol, asebotoxin, rhodotoxin), grayanotoxin II (andromedol), grayanotoxin III (andromedenol).

Phenyl butane derivatives: rhododendrol and its bitter glucoside rhododendrine (betuloside)-flavonoids

EFFECTS

No information is available.

INDICATIONS AND USAGE

Rust-Red Rhododendron is used exclusively in combination preparations in the treatment of hypertonia and muscle and joint rheumatism. In folk medicine, it is used for calculosis, geriatric complaints, gout, high blood pressure, meteorosen-

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The Tan Sheet

Vol. 7; No. 9; Pg. 17

March 1, 1999

SECTION: THE NEWS THIS WEEK

LENGTH: 30 words

TITLE: DIETARY SUPPLEMENT STRUCTURE/FUNCTION CLAIMS: GENERAL NUTRITION

TEXT:

Company..... General Nutrition
Product/Ingredient.. Psyllium
Date..... 1/20/99
Description..... "Psyllium helps clean the colon."

LOAD-DATE: March 8, 1999



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The Tan Sheet

Vol. 6; No. 39; Pg. 16

September 28, 1998

SECTION: THE NEWS THIS WEEK

LENGTH: 70 words

TITLE: DIETARY SUPPLEMENT STRUCTURE/FUNCTION CLAIMS: GNC

TEXT:

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

Company..... GNC Product..... NNW Cleansing Formula, GNC Preventive Nutrition

Colon Care Formula

Date..... 8/27/98

Description.. "Psyllium helps maintain a healthy digestive tract"; "Psyllium helps clean the colon."

LOAD-DATE: October 9, 1998



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The Tan Sheet

Vol. 6; No. 35; Pg. 18

August 31, 1998

SECTION: THE NEWS THIS WEEK

LENGTH: 122 words

TITLE: DIETARY SUPPLEMENT STRUCTURE/FUNCTION CLAIMS: BMK INTERNATIONAL

TEXT:

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..... BMK International Product..... Neo-Concept Lax Away

Date..... 5/28/98

v.005Description.... "Lax Away is a special Chinese formulation of rhubarb and other Chinese herbs. Historically, rhubarb has been used to promote daily regularity. According to traditional Chinese herbalism, elimination issues occur when chi, or vital energy, is blocked. Lax Away works by promoting the movement of chi in the body and dispersing heat, gently promoting daily regularity."

LOAD-DATE: September 3, 1998



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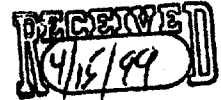
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NOTIFICATION

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

Nature's Essence™ Gastrointestinal Cleanser P2 107

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

"Promote health of gastrointestinal system & normal defecation. Safe & effective supplement proved by uses & studies over 1300 years"

"Nature's Essence™ Gastrointestinal Cleanser promotes health of the gastrointestinal system and helps maintain normal defecation by cleansing out undigested and unhealthy substances from the system through excretion of urine & defecation of feces. The formula is one of the most famous in traditional Chinese medicine. Documented as early as year 652, the safe and effective are proved by its practical uses and studies over 1300 years.

3 List of ingredients of the dietary supplement *Nature's Essence™* Gastrointestinal Cleanser

English Name	Latin Name
Rhubarb	Redix et rhizoma rhei
scutellaria	Redix scutellariae

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The Tan Sheet

Vol. 7; No. 26; Pg. 17

June 28, 1999

SECTION: THE NEWS THIS WEEK

LENGTH: 45 words

TITLE: DIETARY SUPPLEMENT STRUCTURE/FUNCTION CLAIMS: METAGENICS

TEXT:

Company..... Metagenics
Product/Ingredient.. Metabotanica TCB 5
Date..... 4/12/99
Description:..... "Liver/gallbladder support"; "Traditionally
used to balance the energy (ch'i) of the
liver and abdominal area."

LOAD-DATE: July 6, 1999



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The Tan Sheet

Vol. 7; No. 26; Pg. 16

June 28, 1999

SECTION: THE NEWS THIS WEEK

LENGTH: 47 words

TITLE: DIETARY SUPPLEMENT STRUCTURE/FUNCTION CLAIMS: METAGENICS

TEXT:

Company..... Metagenics
Product/Ingredient.. Ethical Nutrients 5 Branches
Date..... 4/12/99
Description..... "Liver/gallbladder support"; "Traditionally
used to balance the energy (ch'i) of the
liver and abdominal area."

LOAD-DATE: July 6, 1999

peony + turmeric



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7375 '99 MAY 26 A9:47

Notice is hereby given pursuant to the requirements of section 403(r)(6)(21 U.S. C. 343(r)(6) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Metagenics, Inc. with its principal place of business at 971 Calle Negocio, San Clemente, California 92673, (714) 366-0818, has commenced marketing the following dietary supplements bearing the following statement(s) on the label and/or in the labeling:

METAGENICS BRAND

Name of Supplement	Name of Ingredient or Supplement that is Subject to the Claim	Text of Claim
BIOPURE PROTEIN™	Whey Protein Concentrate	<p>It is ideal nutritional support for individuals who wish to add a high quality protein to their diet to help promote optimal health and well-being.</p> <p>The high concentrations of naturally occurring, bioactive immunoglobulins in BioPure Protein supports the immune system and are believed to promote health, efficient intestinal function.</p> <p>BioPure Protein has been developed specifically for people wanting to improve general health and support their immune system.</p> <p>It helps many users maintain and gain weight and is ideally suited to improve body compositions and lean muscle mass.</p>

BIO-ZYME™	Chymotrypsin; Trypsin	<p>Bio-Zyme is a proteolytic enzyme formula designed to support tissue health.</p> <p>Proteolytic enzymes function to help break down the bonds that hold protein molecules together.</p>
CAL-APATITE PLUS™	Calcium; Ipriflavone; Vitamin D	<p>Ipriflavone is a unique isoflavone derivative that helps support positive bone metabolism.</p> <p>Vitamin D, an essential nutrient for the maintenance of healthy bones, promotes intestinal calcium absorption and helps to regulate calcium homeostasis in the body.</p>
FEM SOOTHE™	Vitamin B6; Magnesium; Cramp Bark Root; Ginger Rhizome; Wild Lettuce Leaf; Dong Quai Root; Black Cohosh Root	<p>Supports uterine function during menses.</p> <p>A specialized blend of Eurasian and Native American herbal extracts such as cramp bark and black cohosh, herbs traditionally used to support uterine function during menses.</p> <p>Features the added benefits of magnesium to help support muscle relaxation and vitamin B6 to help support healthy hormone metabolism.</p> <p>These unique ingredients, combined with magnesium and vitamin B6, provide support for the uterus and associated tissues.</p>
MICROBEX®	Old Man's Beard; Grapefruit Seed Extract; Oregon Grape Root; Barberry Root Bark 4:1 Extract; Goldenseal Root 4:1 Extract; Cat's Claw Vine	<p>Herbal formula to support intestinal health.</p> <p>A specially formulated blend of select herbs and herbal extracts that have traditionally been used to support a healthy intestinal environment.</p>

ETHICAL NUTRIENTS BRAND

Name of Supplement	Name of Ingredient or Supplement that is Subject to the Claim	Text of Claim
CHYMOZYME™	Chymotrypsin; Trypsin, Raw pancreas concentrate	Designed to support normal tissue formation. Proteolytic enzymes function to help break down the bonds that hold protein molecules together.
FUNCTIONAL GREENS®		Provides excellent nutritional support for general health and well-being.
HEART GLANDULAR PLUS™	Taurine; Magnesium; Potassium; Calcium; Raw Heart Concentrate; Selenium; Chromium; Hawthorn berry; Gentian; Green Pea Concentrate	A unique blend of mineral aspartates, raw heart concentrate, taurine and specialty herbs, including Hawthorn berries designed to provide nutritional support to the cardiovascular system.
STRESS RESCUE™	Rehmannia root; Schisandra fruit; Jujube fruit; Dong quai root; Asparagus root; Ophiopogon root; Scrophularia root; Codonopsis root; Salvia root; Poria Sclerotium; Polygala root; Platycodon root	Herbal stress formula. A classic combination of select Chinese herbs traditionally used to promote inner peace. This ancient stress formula is believed to bring balance and harmony to the body and to help fend off the effects of daily stress. "Nourish the heart" and "maintain a calm spirit," using Stress Rescue from Ethical Nutrients, a classical Chinese stress formula.
→ 5 Branches™	Peony & Turmeric Combination	Liver/Gallbladder support. Traditionally used to balance the energy (ch'i) of the liver and abdominal area.

		This time-honored traditional Chinese formula is designed to balance the energy (ch'i) of the liver and digestive system.
6 Immortals™	Rehmannia & Cornus Combination	Generates vital moisture. This time-honored formula is designed to nourish and support kidney "yin," the "water element" of the body.
8 Treasures™	Dong Quai & Codonopsis Combination	Menstrual & Post-Menstrual Formula Traditionally used to support a healthy, normal menstrual cycle.
Central Palace™	Poria & Pueraria Combination	Stomach support formula. Traditionally used to support normal, healthy digestive function
Gentle Night™	Polygala & Zizyphus Combination	Promotes inner peace. The formula in Gentle Night has been traditionally used to quiet the heart and maintain a calm spirit.
Golden Crane™	Eucommia & Cinnamon Combination	Joint mobility support. Traditionally used to help promote the flow of ch'i through the joints. The combination of herbs in this formula have been traditionally used to build and circulate the "ch'i" to the joints, encouraging healthy movement.
Great Dragon™	Astragalus & Dipsacus Combination	Promotes vital heat and ch'i. Traditionally used to promote kidney yang and ch'i. The herbs in this formula are believed to build "ch'i," promoting normal warmth and energy production.

Jade Empress™	Bupleurum & Peony Combination	<p>Premenstrual Support.</p> <p>This formula has been traditionally used to support liver function as a means of providing premenstrual support.</p> <p>Traditionally used to "open" the liver and promote liver harmony.</p>
Supreme Ch'i™	Codonopsis & Hawthorn Combination	<p>Supports normal digestion.</p> <p>Traditionally used to support healthy digestive function.</p> <p>This formula contains a combination of herbs that have been traditionally used to support the normal breakdown of foods and utilization of the nutrients found in those foods.</p>
Purge Fire™	Gentian & Gardenia Combination	<p>Supports healthy liver detoxification.</p> <p>Traditionally used in China to support and balance the liver meridian.</p> <p>A time honored formula that has been traditionally used to help support the liver's role as a purifier or filter of the blood.</p>
Serene Shen™	Schisandra & Scrophularia Combination	<p>Herbal stress formula.</p> <p>Traditionally used to help the body adapt to stress.</p> <p>In China, the formula in Serene Shen is used to bring calm to a troubled "shen" or spirit.</p>
Silver Crane™	Stephania & Achyranthes Combination	<p>Joint support during wet weather.</p> <p>Traditionally used to promote "balance" during wet and windy weather.</p> <p>The combination of herbs in</p>

		this formula is designed to circulate "ch'i" and to help maintain healthy joints in especially damp or humid weather.
Smooth Passage™	Persica & Rhubarb Combination	<p>Bowel Regularity formula.</p> <p>Supports bowel regularity.</p> <p>Traditionally used to help maintain normal stool softness and bowel regularity.</p> <p>Designed to help maintain normal stool moisture content and normal stool softness..</p>
Wind's Gate™	Lonicera & Forsythia Combination	<p>First defense formula.</p> <p>Traditionally used to promote well-being.</p>

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METABOTANICA BRAND

Name of Supplement	Name of Ingredient or Supplement that is Subject to the Claim	Text of Claim
FENUGREEK PLUS™	Fenugreek Seed; Bitter Gourd Fruit; Gymnema Leaf Extract	<p>Features concentrates of three highly valued herbs, traditionally used to support healthy blood sugar metabolism.</p> <p>These herbs are among the leaders in providing natural support for healthy glucose metabolism.</p>
LICORICE PLUS™	Licorice Root Extract; Ashwagandha Root Extract; Rehmannia Root; Chinese Yam Root	<p>Adrenal support formula.</p> <p>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.</p> <p>Ashwagandha, often referred to as "Indian ginseng" is an Ayurvedic herb with renowned adaptogenic properties.</p> <p>Chinese yam and rehmannia are traditionally used to tonify kidney "yin" and are associated with health and vitality.</p> <p>An herbal adaptogen complex designed to support adrenal and immune function.</p>
SINUPLEX™	Ephedra Leaf; Turmeric Rhizome; Ginger Rhizome; Licorice Root; Feverfew Herb	<p>Herbal formula to support respiratory function.</p> <p>Features a balanced blend of ephedra, an herb traditionally used to support respiratory function, with the complementary herbs</p>

		turmeric, ginger, licorice, and feverfew for added support.
TCB 1™	Eucommia & Cinnamon	<p>Joint mobility support.</p> <p>Eucommia and Cinnamon combination has been traditionally used to help promote the flow of ch'i through the joints.</p>
TCB 2™	Stephania & Achyranthes	<p>Joint support during wet weather</p> <p>Traditionally used to promote "balance" during wet and windy weather.</p>
TCB 3™	Schizandra & Scrophularia	<p>Herbal Stress Formula.</p> <p>Traditionally used to help the body adapt to stress.</p> <p>According to Chinese herbal tradition, the herbs in this formula help to harmonize and nourish the kidney and heart.</p>
TCB 4™	Astagalus & Dipsacus	<p>Promotes vital heat & ch'i.</p> <p>Traditionally used to promote kidney yang and ch'i.</p>
TCB 5™	Peony & Turmeric	<p>Liver/Gallbladder support</p> <p>Traditionally used to balance the energy (ch'i) of the liver and abdominal area.</p>
TCB 6™	Poria & Pueraria	<p>Stomach support formula.</p> <p>Traditionally used to promote healthy digestive function.</p> <p>Designed to nourish and harmonize the normal downward flow of energy (ch'i) within the stomach channel or meridian.</p>
TCB 7™	Rehmannia & Cornus	<p>Generates vital moisture.</p> <p>Traditionally used to nourish kidney yin.</p>
TCB 8™	Dong Quai & Codonopsis	Post-menstrual formula.

		<p>Traditionally used to support female health.</p> <p>Traditionally used to support healthy blood and the circulatory system.</p>
TCB 9™	Gentian & Gardenia	<p>Supports healthy liver detoxification.</p> <p>Traditionally used to support and balance the liver meridian.</p>
TCB 10™	Codonopsis & Hawthorn	<p>Supports normal digestion.</p> <p>Traditionally used to support healthy digestive function.</p>
TCB 12™	Polyala & Ziziphus	<p>Promotes inner peace.</p> <p>Traditionally used to "maintain a calm spirit and quiet the heart."</p> <p>The herbs in this formula are thought to help balance the flow of energy through the heart.</p>
TCB 13™	Persica & Rhubarb	<p>Bowel Regularity Formula.</p> <p>Traditionally used to help maintain normal stool softness and bowel regularity.</p> <p>Provides gentle, non-cathartic, and non-purgative support for the lower colon ch'i.</p>
TCB 14™	Tricosanthes	<p>Traditionally used to support carbohydrate metabolism.</p> <p>May help balance the flow of energy through the meridians of the lung, spleen, and heart.</p>
TCB 16™	Lonicera & Forsythia	<p>First Defense Formula.</p> <p>Traditionally used to promote well-being.</p>

METAPHARMA BRAND

Name of Supplement	Name of Ingredient of Supplement that is Subject to the Claim	Text of Claim
MENOBALANCE™	Rutin; Vitamin C; PABA; Pantothenic Acid; Vitamin B6; Vitamin E; Black Cohosh Root; Chinese Gentian Root; Chasteberry Fruit; Valerian Root; Motherwort Herb; Licorice Root	<p>Natural menopausal support.</p> <p>The formula is prepared with traditional herbal extracts and antioxidant vitamins C and E to support balance during menopause and help maintain cardiovascular health, along with specially selected herbs and B vitamins that support the adrenal glands' adaptive response.</p> <p>The formula features the significant phytonutrient benefits of black cohosh extract, circulatory support from the flavonoid, rutin and the peaceful influence of valerian, motherwort and vitamin B6.</p> <p>Provides nourishment for the mid-life woman or those who desire increased phytoestrogen intake.</p> <p>Unique features include:</p> <ul style="list-style-type: none"> - Nutrients that support the adrenal glands' adaptive response. - The significant phytonutrient benefits of black cohosh extract. - Cardiovascular support from vitamin E. - The peaceful influence of valerian, motherwort, and vitamin B6.
MENSTRELAX™	Vitamin B6; Magnesium; Cramp Bark Root; Blue Cohosh Root; Wild Lettuce Leaf; Dong Quai Root	A specialized blend of Eurasian and Native American herbal extracts such as cramp bark and black cohosh, herbs traditionally used to support uterine function during menses.

		<p>These unique ingredients, combined with magnesium and vitamin B6 provide support for the uterus and associated tissues.</p> <p>This unique herbal formula features the added benefits of magnesium to help support muscle relaxation and vitamin B6 to help support health hormone metabolism.</p>
SELECT C-500™	Vitamin C	<p>Supports immune function by promoting increased natural killer cell activity and increased white blood cell movement to the site of action.</p> <p>In addition to its immune support function and well-known antioxidant properties, vitamin C is essential for the production of collagen and connective tissue.</p>
SELECT C-1000™	Vitamin C	<p>Supports immune function by promoting increased natural killer cell activity and increased white blood cell movement to the site of action.</p> <p>In addition to its immune support function and well-known antioxidant properties, vitamin C is essential for the production of collagen and connective tissue.</p>

THE UNDERSIGNED CERTIFIES THAT THE INFORMATION CONTAINED IN THIS NOTICE IS COMPLETE AND ACCURATE AND THAT METAGENICS, INC. HAS SUBSTANTIATION THAT THE STATEMENTS CONTAINED HEREIN ARE TRUTHFUL AND NOT MISLEADING.

April 12, 1999

BY:

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Its Director of Research and Development

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The Tan Sheet

Vol. 7; No. 9; Pg. 17

March 1, 1999

SECTION: THE NEWS THIS WEEK

LENGTH: 30 words

TITLE: DIETARY SUPPLEMENT STRUCTURE/FUNCTION CLAIMS: GENERAL NUTRITION

TEXT:

Company..... General Nutrition
Product/Ingredient.. Psyllium
Date..... 1/20/99
Description..... "Psyllium helps clean the colon."

LOAD-DATE: March 8, 1999



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The Tan Sheet

Vol. 6; No. 39; Pg. 16

September 28, 1998

SECTION: THE NEWS THIS WEEK

LENGTH: 70 words

TITLE: DIETARY SUPPLEMENT STRUCTURE/FUNCTION CLAIMS: GNC

TEXT:

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

Company..... GNC Product..... NNW Cleansing Formula, GNC Preventive Nutrition

Colon Care Formula

Date..... 8/27/98

Description.. "Psyllium helps maintain a healthy digestive tract"; "Psyllium helps clean the colon."

LOAD-DATE: October 9, 1998



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