



JUL 12 2002

Ms. Gammy C.Y. Kwok
Director
Herbs Generation International Ltd.
Room 1303
1 Lyndhurst Tower
1-7 Lyndhurst Terrace
Central, Hong Kong

Dear Ms. Kwok:

This letter acknowledges receipt of a new dietary ingredient notification, dated April 18, 2002, to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 350b(a)(2). On April 29, 2002, FDA received and filed your notification concerning the substance *Ganoderma lucidum* Spore Powder (Shell-Broken) that you assert is a new dietary ingredient. Subsequently, on June 10, 2001, we received your letter dated June 3, 2002, inquiring about the status of your notification.

In accordance with 21 U.S.C. 350b(a)(2), a manufacturer or distributor of a dietary supplement that contains a new dietary ingredient must submit certain information to FDA at least 75 days before the dietary ingredient is introduced or delivered for introduction into commerce. This information must include the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the new dietary ingredient is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B), because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness and injury.

Federal regulations found at 21 CFR 190.6 specify the requirements for a premarket notification of a new dietary ingredient. We have enclosed a copy of the section of the CFR that addresses these requirements. Information that may further assist you is found at our website, <http://www.cfsan.fda.gov/~dms/ds-ingrd.html>.

The notification you sent us concerning *Ganoderma lucidum* Spore Powder (Shell-Broken) is incomplete and does not meet the minimum requirements of 21 CFR 190.6 because it fails to:

- Completely identify the Latin binomial name of *Ganoderma lucidum*, which must include the name(s) of the author(s) who published the botanical name.
- Clarify the physical form(s) of the new dietary ingredient you intend to market as a dietary supplement. Your letter identifies the new dietary ingredient as

Ganoderma lucidum Spore Powder (Shell-Broken), however, the accompanying summary report by the Chinese Academy of Sciences discusses both *Ganoderma lucidum* Spore Powder and *Ganoderma lucidum* Spore Oil.

- State the level(s) or amount of the new dietary ingredient that would be provided in each of the dietary supplements you intend to market (e.g., amount per capsule).
- Fully specify the recommended conditions of use of a dietary supplement containing the new dietary ingredient including: a description of the target population of consumers in terms of gender, age, and any subgroups that should be excluded (e.g., infants, children, pregnant, or lactating women, persons with certain medical conditions or those taking particular medications); and duration of use (e.g., for a certain number of months versus every day for a lifetime).
- Provide sufficient evidence that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe when used at your recommended level of intake. Your notification does not clarify: 1) whether *Ganoderma lucidum* Spore Powder (Shell-Broken) is identical in composition and processing to the *Ganoderma lucidum* spore cited in the Chinese Academy of Sciences literature you submitted; or 2) how the use of *Ganoderma lucidum* in traditional Chinese medicine is relevant to the intended conditions of use for *Ganoderma lucidum* Spore Powder (Shell-Broken) in terms of the level, frequency, and duration of use and the target population of consumers.
- Further, the information you submitted from the Chinese Academy of Sciences represents a summary report that is not accompanied by copies of the actual studies cited to verify whether they were designed and conducted in a way to achieve scientifically reliable results. Other information in your notification appears to be selected pages printed from commercial or promotional Internet sites rather than from authoritative scientific sources. All such copies provided in a notification must be full descriptions of the studies, not abstracts or summaries. If they are written in a foreign language, they must be accompanied by accurate and complete English translations. Please ensure that all photocopies you send us are clearly legible with no missing lines of text due to poor alignment of the paper when copying.

You submitted pages from an Internet site on the product "GURU Fully Sporoderm-broken Pure Ganoderma Sporo-pollen Capsule." This site states "this product has passed the strict examination and test by FDA of the USA and has been authenticated for health product by FDA." That statement is incorrect. New dietary ingredients for use in supplements that FDA has reviewed through the premarket notification process are not "authenticated," "approved," or "authorized" by the agency. In addition, FDA does not test ingredients that are reviewed through the new dietary ingredient notification process.

For the reasons discussed above, the information in your notification does not provide an adequate basis to conclude that the use of *Ganoderma lucidum* Spore Powder (Shell-Broken) in a dietary supplement is reasonably expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 321(g)(1)(B) as a dietary supplement that contains *Ganoderma lucidum* Spore Powder (Shell-Broken) for which there is inadequate information to provide

reasonable assurance that it does not present a significant or unreasonable risk of illness or injury. Introduction of such products into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

If you desire, you may send us the required information to correct the deficiencies in your current notification by submitting a new notification, in triplicate, that is complete and fully complies with 21 CFR 190.6. The date we receive this additional information is considered the new filing date for your new notification.

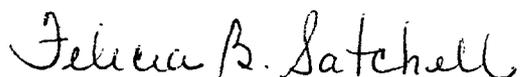
Although not required, if you decide to submit a new notification, we would appreciate your sending us an additional two copies for a total of five copies (i.e., original and four copies) to facilitate our internal administrative processing of the notification. Please make sure that all copies you send us contain the same information in accordance with 21 CFR 190.6.

Your notification will be kept confidential for 90 days after the filing date. Therefore, after July 28, 2002, the notification, its addenda and related correspondence from FDA will be placed on public display at FDA's Dockets Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information that is in the notification will not be disclosed to the public.

Prior to July 28, 2002, you may wish to identify in writing specifically what information you believe is proprietary. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notification should be redacted before it is posted at Dockets.

We noticed that your notification does not include either a phone or facsimile (fax) number or an electronic mail address as other ways to contact you. Although you are not required to provide us with this information, we would appreciate your sharing it with us, if it exists, as quicker ways to communicate with you. If you have additional questions, please contact us at (301) 436-2371.

Sincerely yours,



Felicia B. Satchell
Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Enclosure

[Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2001]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR190.6]

[Page 569-570]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 190--DIETARY SUPPLEMENTS--Table of Contents

Subpart B--New Dietary Ingredient Notification

Sec. 190.6 Requirement for premarket notification.

(a) At least 75 days before introducing or delivering for introduction into interstate commerce a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered, the manufacturer or distributor of that supplement, or of the new dietary ingredient, shall submit to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, information including any citation to published articles that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. An original and two copies of this notification shall be submitted.

(b) The notification required by paragraph (a) of this section shall include:

(1) The name and complete address of the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient;

(2) The name of the new dietary ingredient that is the subject of the premarket notification, including the Latin binomial name (including the author) of any herb or other botanical;

(3) A description of the dietary supplement or dietary supplements that contain the new dietary ingredient including:

(i) The level of the new dietary ingredient in the dietary supplement; and

(ii) The conditions of use recommended or suggested in the labeling of the dietary supplement, or if no conditions of use are recommended or suggested in the labeling of the dietary supplement, the ordinary conditions of use of the supplement;

(4) The history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which the distributor or manufacturer of the dietary supplement that contains the new dietary ingredient has concluded that the new dietary supplement will reasonably be expected to be safe. Any reference to published information offered in support of the notification shall be

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accompanied by reprints or photostatic copies of such references. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation; and

(5) The signature of the person designated by the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient.

(c) FDA will acknowledge its receipt of a notification made under section 413 of the Federal Food, Drug, and Cosmetic Act (the act) and will notify the submitter of the date of receipt of such a notification. The date that the agency receives the notification submitted under paragraph (a) of this section is the filing date for the notification. For 75 days after the filing date, the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient shall not introduce, or deliver for introduction, into interstate commerce the dietary supplement that contains the new dietary ingredient.

(d) If the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient, provides additional information in support of the new dietary ingredient notification, the agency will review all submissions pertaining to that notification, including responses made to inquiries from the agency, to determine whether they are substantive and whether they require that the 75-day period be reset. If the agency determines that the new submission is a substantive amendment, FDA will assign a new filing date. FDA will acknowledge receipt of the additional information and, when applicable, notify the manufacturer of the new filing date, which is the date of receipt by FDA of the information that constitutes the substantive amendment.

(e) FDA will not disclose the existence of, or the information contained in, the new dietary ingredient notification for 90 days after the filing date of the notification. After the 90th day, all information in the notification will be placed on public display, except for any information that is trade secret or otherwise confidential commercial information.

(f) Failure of the agency to respond to a notification does not constitute a finding by the agency that the new dietary ingredient or the dietary supplement that contains the new dietary ingredient is safe or is not adulterated under section 402 of the act.

[62 FR 49891, Sept. 23, 1997, as amended at 66 FR 17359, Mar. 30, 2001]



Herbs Generation International Ltd.

草 姬 國 際 有 限 公 司

18th April, 2002

To: Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration, 5100 Paint Branch Parkway
College Park, MD, 20740-3835

Dear Sirs/Madam,

**Re: Submission of a Premarket Notification for a new dietary Ingredient to
FDA---Ganoderma Lucidum Spore powder (Herbs Generation Ganoderma
Lucidum Spore (100%))**

We are writing in submitting the notifications for new dietary ingredients, the required information as follows:

Company Name : Herbs Generation International Limited
Contact person : Miss Gammy C. Y. Kwok
Address : Rm 1303, 13/F, 1 Lyndhurst Tower, 1-7 Lyndhurst Terrace,
Central, Hong Kong

Name of the New

Dietary Ingredient : Ganoderma Lucidum Spore Powder (Shell- broken)
Ingredient Description: 100% Ganoderma Lucidum Spore Powder contains
Triterpene, polysaccharides, polypeptide, glucopeptide
Adenosine, enzyme, alkaloid, organic germanium and
Multiple trace elements

Conditions of use : Able to help enhance the immune system, promote good
Health, improve the body metabolism, improve the skin
Texture and complexion, and prevent pre-mature aging.
Normal health: 2 capsule each time/twice per day

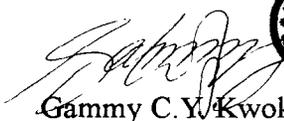
History of use or

Evidence of safety of use: Please refer to the attached information done by the
Chinese Academy of Sciences

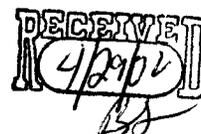
Should you need further information, please feel free to contact the undersigned.

Thanks!

Best regards


Gammy C. Y. Kwok

Director





Herbs Generation International Ltd.

草 姬 國 際 有 限 公 司

18th April, 2002

To: Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)
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Food and Drug Administration, 5100 Paint Branch Parkway
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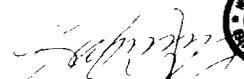
History of use or

Evidence of safety of use: Please refer to the attached information done by the
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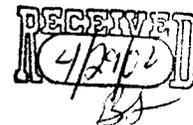
Should you need further information, please feel free to contact the undersigned.

Thanks!

Best regards


Gammy C. Y. Kwok

Director



The 4th Way For Cancer Therapy
抑制肿瘤的第四种方式

中 科 灵 芝

ZHONGKE® Shell-broken G.Lucidum Spore



中国科学院
ACADEMIA SINICA

前言 Foreword

灵芝是中国古老的药食品，三千年以前已经用来治疗疾病，显著的效果为其赢来“东方神奇仙草”的美誉，灵芝“起死回生”的传说更是古老相传。灵芝孢子是灵芝的精华，约1000克灵芝收集1克灵芝孢子，中国科学院在海拔1000公尺以上、生态环境优良的中国黄山建立灵芝基地培植纯种赤芝，并运用现代技术使灵芝孢子在常温下全部破壁，消除了几丁质内壁造成的吸收障碍，这种纯物理技术丝毫不损害灵芝孢子的活性物质，使其被人体全面吸收并产生效果。

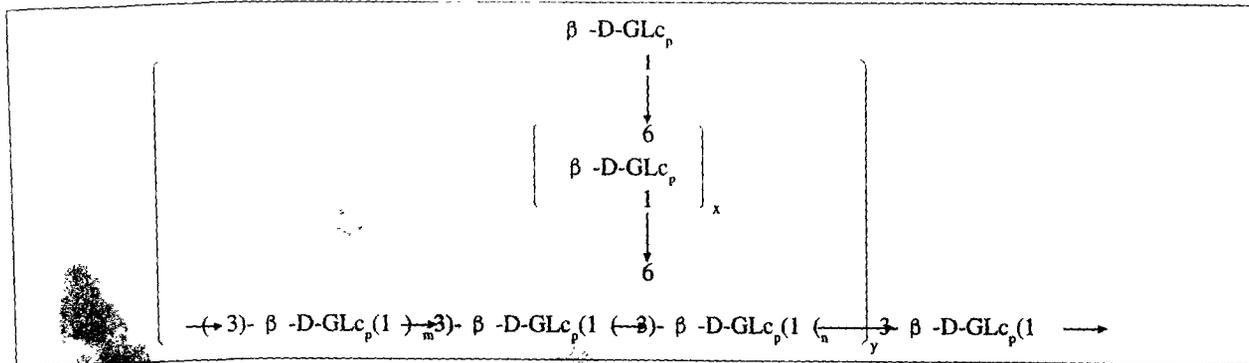
As a medicinal nutriment, ganoderma lucidum has a very long history. More than 3000 years ago, our ancestors began to use it to cure diseases and it was praised as the "Oriental Miracle Herb" for its remarkable effect. It is a household legend that ganoderma lucidum "brings the dead back to life". Ganoderma lucidum spore is the essence of ganoderma lucidum and only one gram of ganoderma lucidum spore can be derived from 1000 grams of ganoderma lucidum. The Academia Sinica has founded its pure ganoderma lucidum cultivation base for planting pure, the est of Ganoderma Karst on Mt. Huangshan over 1000m above sea level with excellent ecological environment and has the shells completely broken at normal temperature with modern techniques. Such way can solve the absorption problem arising from the internal walls of chitin. This completely physical technology does no damage to the active elements of ganoderma lucidum spore and facilitates the absorption by human body to achieve excellent effect.

作用机理 Functional Mechanism

一、成分 Ingredients:

中科灵芝孢子是三萜、多糖、多肽、糖肽、腺甙、酶、生物碱、有机锗及多种微量元素的组合体，它们具有强烈的生理活性，单独或协同作用。

Zhongke ganoderma lucidum spore is a combination of triterpene, polysaccharides, polypeptide, glucopeptide, adenosine, enzyme, alkaloid, organic germanium and multiple trace elements and thus it is endowed with strong physiological activity, suitable for independent application or integrated application.



具有抗肿瘤作用的灵芝多糖的基本结构

Basic Structure of G. Lucidum Polysaccharides with Anti-tumor Functions

ganoderic acid U $C_{30}H_{48}O_4$	II: $R_1=OH$ $R_2=R_3=R_4=H$	ganoderic acid Z $C_{30}H_{48}O_4$	III: $R_1=\beta-OH$ $R_1=R_2=R_3=R_4=OH$
ganoderic acid V $C_{32}H_{48}O_5$	II: $R_1=O$ $R_2=OH$ $R_3=OAc$ $R_4=H$	ganoderic acid X $C_{32}H_{48}O_5$	III: $R_1=-OH$ $R_2=-OAc$ $R_3=H$ $R_4=COOH$ $R_5=CH_3$
ganoderic acid W $C_{24}H_{32}O_7$	II: $R_1=R_3=OAc$ $R_2=OH$ $R_4=H$	ganoderic acid Y $C_{24}H_{32}O_7$	III: $R_1=-OH$ $R_2=R_3=H$ $R_3=H$ $R_4=COOH=CH_3$

具有抗肿瘤作用的三萜类的分子式

Molecular Formula of Anti-tumor Triterpene

二、抑瘤机制 Tumor Restriction Mechanism:

中科灵芝孢子主要通过刺激体内本来固有的具有细胞毒活性的效应细胞*和细胞因子**,以增强网状内皮系统的生物活性,杀伤肿瘤细胞,达到控制肿瘤生长或使肿瘤消退的目的。

- 1、活化机体的效应细胞*,增强机体的毒杀肿瘤和溶瘤能力,使机体的自身肿瘤杀伤活性转阳率超过80%。
- 2、诱导细胞因子**的分泌与合成,增强机体毒杀肿瘤细胞能力和活化效应细胞,保护正常细胞。
- 3、抑制肿瘤细胞产生的免疫抑制因子,使肿瘤细胞暴露在杀伤细胞的杀伤力下。
- 4、抑制肿瘤细胞产生促生长因子。
- 5、修饰和增强机体对癌效应的敏感性,增强机体的效应能力。
- 6、清除自由基,在体内表现强超氧化物歧化酶(SOD)活性。
- 7、促进骨髓细胞DNA、RNA、蛋白质的合成,加速骨髓细胞的分裂增殖,提高骨髓造血功能。
- 8、降低癌细胞表面电位,诱导癌细胞基因再次突变并启动调亡程序。
- 9、具有毒杀肿瘤细胞作用(灵芝酸部分),但机制尚不明确。

动物实验结果显示中科灵芝孢子对多种移植性肿瘤具有抑制作用。

Saroma 180肉瘤: 86.9~91.0% 白血病P388: 66.5~78.4% 肝癌AH-13、AH-7974、AH-66F: 65.1~71.0% 劳卫氏癌: 81.5~89.6% 恶性肌纤维瘤: 86.0~98.0% 艾氏腹水瘤: 79.3~87.6% 腹水型肝HEPS癌: 44.7~56.0%

*效应细胞: T细胞、巨噬细胞(MΦ)、自然杀伤细胞(NK)、淋巴细胞激活的杀伤细胞(LAK)

**细胞因子: 干扰素(IFN)、白细胞介素(IL)、肿瘤坏死因子(TNF)、克隆刺激因子(CSF)

By stimulating the body-intrinsic effector cell* and cell factor** with cytotoxicity, Zhongke ganoderma lucidum spore is to promote the biological activity of retothelium and kill the tumor cells, achieving the purpose of restricting the growth of tumor or eliminating tumor.

1. Activates effector cells of body, enhances the ability of body to kill tumuor and of oncolytic, raises the positive-transfer rate of the activity of damaging the tumour over 80%.
2. Induces the secrection and synthesis of cells factor, enhances the ability of body killing tumour, activates effector cell, and protects normal cells.
3. Restrains immene suppressor factor produced by tumour cells, makes tumour cell exposed to killer cells.
4. Restrains tumour cells from producing growth promotion.
5. Repairs and enhances the sensibility of body to cancer effector, enhances adaptability of body.
6. Eliminates radicals so as to show strong activity of superoxide dismutase in body.
7. Improves the synthesis of marrow cells DNA, RNA and protein, accelerates splitting and propagation of marrow cells, and enhances blood producing function of marrow.
8. Reduces surface potential of cancer cells, inducts cancer cells gene to mutate again and initiate its fading program.
9. Kills tumour cells, but its mechanism remains unknown so far.

Zooperal result shows that Zhongke Ganoderma Lucidum Spore has the inhibitive function to transplantable tumors.

Sarcoma 180: 86.9~91.0% Leukemia P388: 66.5~78.4%

Liver Cancer AH-13,AH-7974, AH-66F: 65.1~71%

Rous Cancer: 81.5~89.6% Malign Fibroma: 86.0~98.0%

EC Ehrlich Carcinoma: 79.3~87.6% Ascitic HEPS Liver Cancer: 44.7~56.0%

*Effector Cell: T cell, macrophage (MΦ), natural killer (NK) and limph-cell activated killer (LAK).

**Cell Factor: interferon (IFN), interneukin (IL), tumor necrosis factor (TNF) and clone stimulus factor (CSF).

三、毒理学 Toxicology:

- 1、急性经口毒性实验：雌雄小鼠LD₅₀均大于21.5g/kg。
- 2、Ames 试验：对标准测试菌 TA97a、TA98、TA100 和 TA102，平板掺入法，剂量达 5000ug/皿，加及不加 S₉，均未检出明显的诱变活性。
- 3、小鼠骨髓嗜多染红细胞微核试验：剂量达 10g/kg 体重，雌雄小鼠均未检出对骨髓嗜多染红细胞的诱变活性。
- 4、小鼠睾丸初级精母细胞染色体的诱变活性：剂量达 10g/kg 体重，未检出对雄性小鼠睾丸初级精母细胞染色体的诱变活性。

结论：中科灵芝孢子属无毒级。

1. Acute Toxicity Experiment: LD₅₀ for both female and male mice is over 21.5g/kg.
2. Ames Experiment: Standard test bacteria TA97a, TA98, TA100 and TA102, flat oozing process, dosage 5000ug/one, with adding S₉ or not, which shows no obvious sign of induction activity.
3. Polychromatophilic normocyte micronucleus test on mice bone marrow: Dosage is up to 10g/kg (weight) and no induction activity of the male and female mice has been detected on polychromatophilic normocyte of bone marrow.
4. Induction activity of primary spermatocyte chromosome of mice spermary. Dosage is up to 10g/kg (weight) and no induction activity has been detected on primary spermatocyte chromo some of male mice spermary.

辅助抑制肿瘤的应用 Auxiliary application to cancer inhibition

- 1、增强治疗效果：与放疗、化疗一起使用可增强抑瘤效果，其中化疗效果提高的占 63.2~71.5%，23% 治疗时间缩短；放疗效果有提高的占 24.5~33.9%。
- 2、创造治疗机会：使只能保守治疗、濒临死亡的病人恢复治疗指征，能继续接受治疗、化疗的占该阶段病人的 11.3~20.9%，手术后服用提高伤口愈合、身体转好速度，使病人尽快接受放疗和化疗。
- 3、防止肿瘤迅速扩散。
- 4、降低毒副作用：在放、化疗中，放化疗后均降低毒副作用，减轻骨髓抑制。80.6~87.0% 的患者白细胞保持在允许范围内；55.8~64.2% 的患者不呕吐，其余在 1~3 天内可止吐；17.5~23% 患者脱发轻微；95% 以上饮食、睡眠正常。
- 5、提高生命质量：在整个患病期内生命质量均有改观，100% 饮食增加，100% 睡眠改善，100% 精神体力转好，90% 白细胞恢复正常人水平，70% 疼痛减轻，60% 便秘改善，65% 的卧床病人能起床活动。
- 6、延长生存时间：以不同剂量服用的患者均 100% 超过预期生存时间。
- 7、在一定程度上缓解恶性腹水、胸腔积水。

1. Promote the curing effect: Cancer-inhibitive effect can be increased when used with radiation therapy and chemotherapy. For 63.2~71.5% of all the cases, the therapeutic effect is enhanced (for 23%, the therapeutic period is shortened) and for 24.5~33.9%, the effect of radiation therapy is enhanced.
2. Create therapeutic opportunity: for cases that therapeutic indication is restored for dying patients and patients receiving the conservative treatment, of which, 11.3~20.9% can resume radiation therapy and chemotherapy. After operation, it can help post-operational cut to heal rapidly and recover physically so as to receive radiation therapy and chemotherapy as soon as possible.
3. Prevents tumor from rapid diffusion.
4. Reduces side effect: the toxic effect has been reduced to low during radiation therapy and chemotherapy and the bone marrow is eased. For 80.6~87.0% of the cases, the white cell is kept within the limit; for 55.8~64.2% of the patients, no vomiting and the rest can stop vomiting within 1~3 days; for 17.5~23%, they suffer from slight lapsus pilorum; Over 95%, with normal sleep and diet.
5. Improve Life Quality: during the whole lapse, the life quality is considerably improved. Increased diet: 100%; Better sleep: 100%; restored vitality: 100%; restored normal standard in white cell: 90%; relieved from pain: 70%; improved opilation: 60% and bedridden patients who can walk about now: 65%.
6. Prolonged Survival: 100% patients who take the medicine in various dosages can outlive the estimated survival.
7. Relieve malign peritoneal fluid and hydrothorax to certain degree.

用法与用量 Instructions & Dosages

状 况	1、不能进行手术、放疗、化疗； 2、确诊后到手术（直接或化疗）前； 3、放、化疗前、放、化疗中白细胞、 血色素异常； 4、进入晚期（M）	1、手术后到放、化疗前； 2、放、化疗中； 3、放、化疗结束后半月内； 1、2、3各项化验指标均正常	因肿瘤引起 的疼痛	肿瘤恢复期
名 称				
灵芝孢子 胶囊	10粒/次，日两次 早晚空腹服用	5粒/次，日三次 空腹服用	10粒/次 日三至四次	5~6粒/次 日二次
灵芝精粉 胶囊	5粒/次，日两次 与灵芝孢子同服	5粒/次，日三次 与灵芝孢子同服	5粒/次，日三至四 次 与灵芝孢子同服	5~6粒/次，日二 次 与灵芝孢子同服

Status	1.No operation, radiation therapy or chemotherapy available. 2.Postconfirmation to pre-operation (chemotherapy). 3.Pre-or inter-radiation therapy and chemotherapy with abnormal white blood cell or hemachrome. 4.Late period (M).	1.Pre-operation and radiation therapy and chemotherapy. 2 Inter-radiation therapy and chemotherapy. 3.Within 15 days after radiation therapy and chemotherapy. Every index of chemical examinations 1, 2 & 3 are O. K.	Pains caused by tumor.	Convalescence from tumor.
Name				
Ganoderma Lucidum Spore Capsule	10capsules/once, twice a day Take before meal in the morning & evening.	5 capsules/once, thrice a day. Take before meal.	10 capsules/once. 3 or 4 times per day.	5~6 capsules/once. Twice per day.
Ganoderma Lucidum Capsule	5 capsules/once, twice a day Take with the above.	5 capsules, thrice a day. Take with the above.	5capsules/once. 3 or 4 times per day. Take with the above.	5~6 capsules/once. 3 or 4 times per day. Take with the above.

其它作用及用量 Other Functions & Dosages

一、心脑血管病 Cardiovascular and cerebrovascular diseases:

破壁灵芝孢子降低全血粘度和血浆比粘度，抑制血小板凝聚反应，防止血栓形成，改善患病时的血液流变学障碍，扩张冠状动脉的侧支，增加缺血区心肌的供血和供氧量，缓解或减轻心绞痛症状，改善心电图表现。用量：6~12粒/日

Shell broken Ganoderma Lucidum Spore can reduce the viscosity of the whole blood and, restrain the reaction of platelet aggregation, prevent the formation of thrombus, improve the rheological barrier of the blood, enlarge the branch of the coronary artery, increase the supply of blood and oxygen and blood to the ischemia region, relieve angina and improve the behavior of the electrocardiographic curve. Dosage: 6~12 capsules per day.

二、肝炎和肝硬化 Hepatitis and Liver Sclerosis:

破壁灵芝孢子提供肝代谢和修复所必需的氨基酸、糖和微量元素，促进 H^3 -UR参入肝脏RNA，促进 H^3 -Leu参入血清蛋白质和肝脏蛋白质，增加肝匀浆细胞色素P-450含量，从而促进受损肝细胞的修复。破壁灵芝孢子对病毒性肝炎的有效率为83.2%，对谷丙转氨酶、黄疸指数均有降低的作用，并减少肝小叶炎症细胞浸润。它促进T细胞产生干扰素，为HBV阴转和丙肝治疗提供了途径。用量：1、重症肝炎、肝硬化、肝腹水 16~20粒/日 2、HBV携者（大三阳、小三阳） 8~12粒/日

Shell broken Ganoderma Lucidum Spore can provide the indispensable amino acid, saccharin and trace elements to the metabolism and the repairing of liver, stimulate H^3 -UR to ooze into the liver RNA and stimulate H^3 -Leu to ooze into serum protein and liver protein, increase the content of P-450 and stimulate the repair of damaged liver cells. The efficiency of Shell broken Ganoderma Lucidum Spore against virus hepatitis hits 83.2% and it can reduce the index of glutamic aminopherase and jaundice and reduce the inflammatory corpuscle of liver lobulus. It spurs up T cells to produce interferon, supplying the transformation of HBV and the therapy of C hepatitis. Dosage: 1.For Serious hepatitis, liver sclerosis and ascetic fluid 16~20

三、白细胞减少症 Decrement of White Blood Cell:

破壁灵芝孢子促进骨髓细胞蛋白质、核酸的合成，加速骨髓细胞的分裂增殖，迅速解除骨髓抑制，对肿瘤治疗中的放疗、化疗引起的或其它原因引起的白细胞减少症有效，有效率 84.6%。用量：12~20 粒 / 日

Shell broken Ganoderma Lucidum Spore can enhance the symthesis of the marrow cell protein and nucleid acid, speed up the separation and proliferation of marrow cells and relieve the marrow inhibition. It is effective to the white blood cell decrement incurred during the process of radiation therapy, chemotherapy and other reasons and the efficiency of therapy is 84.6%. Dosage: 12~20 capsules/day.

四、慢性支气管炎及哮喘 Chronic Bronchitis and Asthma:

破壁灵芝孢子促进气管的纤毛柱状上皮细胞的再生和气管软骨变形的修复，抑制组织胺的释放和拮抗乙酰胆碱，从而实现对气管平滑肌的解痉。它对慢性支气管炎的咳、痰、喘均有作用，对喘的有效率为 80.0% 用量：6~12 粒 / 日

Shell broke Ganoderma Lucidum Spore can enhance the reproduction of cilium epicyte of the trachea and the repair of the cartilage deformation of the trachea and restrain the release of amine and the rivalry acetylcholine to relieve the spasm of the smooth muscle. It is effective to the cough, sputun and asthma typical of bronchitis and the efficiency to asthma is 80.0%. Dosage:6~12capsules/day

五、糖尿病 Diabetics:

破壁灵芝孢子增加血浆胰岛素浓度、加速葡萄糖代谢，它不仅增加周围组织对糖的利用，还能通过强化参与肝脏糖代谢的各种关键酶的活性提高肝脏葡萄糖的利用。如明显促进肝脏葡萄糖激酶、磷酸果糖激酶葡萄糖-6-磷酸脱氢酶的活性，降低糖原合成酶的活性。用量：8~12 粒 / 日

Shell broke Ganoderma Lucidum Spore can increase the concentration of plasma insulin and speed up the metabolism of glucose. It can not only enhance the utility of saccharine by surrounding tissues but also strengthen the activity of the crucial enzyme through the metabolism of saccharine in the liver to promote the utility rate of saccharine by the liver. For example, it can promote the activity of glucose kinase and glucose-6-phosphate dehydrogenase to decrease the activity of the synthetase. Dosage: 8~12 capsules/day

六、高血压、高血脂 Hypertension and Hypolipemia:

破壁灵芝孢子抑制血管紧张素酶的活性，降低有效率为 87.0%。它明显降低血清中胆固醇、甘油三酯和 β -脂蛋白质的浓度，从而降低血脂，预防脂肪肝。用量：6~12 粒 / 日

Shell broke Ganoderma Lucidum Spore can restrain the activity of antiotensin enzyme and the efficiency is 87.0%. It can obviously reduce the concentration of cholesterol, triglyceride and β -fatty protein to reduce blood fat and prevent hepar adiposum. Dosage: 6~12 capsules/day

七、神经衰弱 Neurataxia:

破壁灵芝孢子对神经衰弱总有效率 96.0%，其中显效 90.0%。一般服用 1~2 周后症状明显改善。用量：

Shell broke Ganoderma Lucidum Spore has a total efficiency rate of 96.0% over Neurataxia and 90% with obvious effect. Generally, one-or two-week treatment with this medicine can improve the conditions obviously. Dosage: 6~12 capsules/day

不良反应及禁忌 Undesirable Reaction & Contraindication

服用中科灵芝孢子无明显不良反应。妊娠期妇女、婴幼儿、蛋白质严重过敏者忌用。

There is no undesirable reaction with these capsules.

Forbidden for pregnant women, babies and people severely allergic to proteins.

结语 Conclusion

灵芝是中华传统医药学宝库中的珍品，东方世界三千年的推崇和神化必然有其道理。中科灵芝孢子是现代灵芝制品的佼佼者，作为BRM（生物调节剂）已广泛用于辅助抑制肿瘤，并收到了良好的效果，为广大肿瘤患者和其他患者带来了生命之光和康复的希望。

Ganoderma Lucidum is a rare gem in the traditional Chinese medicinal treasure house and it has been worshipped and deified for 3000 years by the oriental worle. Zhongke Ganoderma Lucidum Spore is the best of the modern ganoderma lucidum products and has been widely used, as BRM (biological regulating media), to help resist tumors and excellent effect has been achieved, which has brought the hope of life and recovery to those who suffer from cancer or other diseases.

附录 Appendix

灵芝孢子必须破壁后才能发挥作用。

人体细胞是通过分子渗透进行吸收的，灵芝孢子大小和人体红细胞相当，不可能被人体直接利用。从结构上看，灵芝孢子的外层是几丁质孢壁，其成分与核桃壳相当，也可以说灵芝孢子就象缩小3000倍的核桃，坚硬的几丁质紧紧包围着人体需要的分子物质，这些分子物质包括主要抗癌成分多糖类，分子量在40000左右的多糖分子难以透过几丁质的紧密结构进入人体体液。用14倍去离子水煮沸灵芝孢子2小时，其多糖总量仅为同重量破壁灵芝孢子的1/9.2。在另一个实验中，服用未破壁灵芝孢子的病人的排泄物中存在大量完整孢子，部分还能存活。这些实验更加证明，只有打破孢壁，灵芝孢子的功效成分才能被完全吸收利用，无论单独使用灵芝孢子，还是与灵芝精粉、与虫草、与黄芪、与茯苓配伍，破壁，都是不可绕行的必由之路。

再者，新采集的灵芝孢子粉中大部分是未成熟的孢子，未成熟孢子中三萜类含量低且难以破壁。三萜类是灵芝孢子的重要成分，在毒杀肿瘤细胞、止痛、保肝解毒方面具有强烈的活性。破壁的灵芝孢子，必然是成熟的灵芝孢子，破壁的灵芝孢子，可有力保证三萜类的含量。

有人认为长期大量服食未破壁灵芝孢子也会有一定作用，但时间稍长就会形成粪结石。

GANODERMA LUCIDUM SPORE CAN BE EFFECTIVE ONLY WHEN THE SHELLS ARE BROKEN.

The human cell absorbs nutriments via molecular permeation. The spore has the similar size to that of the human red blood cell and so it is impossible to be absorbed. In view of the structure, the outer layer of ganoderma lucidum spore is a wall of chitin and its composition is something like that of the walnut. The ganoderma lucidum spore is a walnut reduced by 3000 times and the rigorous chitin contains the molecule and these molecular matter contains the main anticancer material polysaccharide and the polysaccharide with the molecular weight of 40000 cannot permeate the solid structure of chitin to enter the human humor. Boil the ganoderma lucidum spore for 2 hours in 14x deionized water, the total amount of polysaccharide is only 1/9.2 of that in the shell-broken spore. Another experiment shows that the excrement from patients who took shell-unbroken ganoderma lucidum spore contains a large number of unbroken spores and some of them were even viable. These experiments show that only by breaking the shells of the spores can the efficacy of ganoderma lucidum spore be fully taken use of and absorbed. Whether used independently or with cordyceps, astragalus or poria, it is an indispensable step to break the shell.

In addition, newly collected ganoderma lucidum spore powder contains immature spores and the triterpene content in immature spores is low and it is difficult to break the shells. Triterpene is important composition of the ganoderma lucidum spore and it has great activity in killing tumor cells, relieving pains, protecting the liver and detoxication. Shell-broken spores must be mature spores and only mature ganoderma lucidum spores can guarantee the content of triterpene.

Some people believe that constant taking of shell-unbroken spores is of some effect. This can, however, result in manure calculus.

1g Ganoderma Spore Oil = 20g Ganoderma Spore

1 克油 = 20 克灵芝孢子粉

科
灵芝孢子油

ZHONGKE® Ganoderma Spore Oil



中国科学院
ACADEMIA SINICA

灵芝孢子油是灵芝孢子的主要功效成分

Ganoderma Spore Oil is the active ingredients of Ganderma Spore

灵芝孢子油是灵芝孢子的脂溶性物质，包括全部三萜类和核苷类，与部分水溶性物质（多糖类）经浓缩后的集合，常温下为黄色至金黄色半透明液体。室温置放30天后会出现灵芝多糖的结晶现象。

“中科”灵芝孢子油采用先进的CO₂超临界萃取技术直接从破壁的灵芝孢子中提纯，所提取的灵芝孢子油更纯净、成分更全面，集中了灵芝孢子原生质中的三萜类、多糖类、核苷类等全部有效成分。

由于灵芝孢子的抑瘤作用主要通过三萜成分、多糖成分、核苷成分完成，一般认为，灵芝孢子油正是灵芝孢子中功效成分的集合体。

Ganoderma Spore Oil, a yellow or golden semi-transparent liquid under normal temperature, is the concentration of some water-soluble matters (polyose) and the fat-soluble substances, including all triterpenes and nucleosides, contained in Ganderma Spore. Placed in the room temperature for 30 days, Ganoderma polysaccharide crystal would appear.

Via the advanced CO₂ Super-critical technology, Zhong Ke Ganoderma Spore Oil was extracted directly from broken Ganoderma Spore. Concentrating all the active ingredients, including triterpenes, nucleosides and polyoses, contained in sporoplasm, the Ganoderma Spore Oil is purer and its ingredients more complete.

Because triterpenes, nucleosides and polyoses, contained in Ganoderma Spore Oil, are the three most active ingredients to inhibit the proliferation of tumor, generally, Ganoderma Spore Oil is considered as the assembly of the effective ingredients in Ganoderma Spore.

机理与作用 Mechanism and Function

一、成分 Ingredients:

每100mg“中科”灵芝孢子油含三萜类37mg、多糖11mg、核苷类22mg、脂肪酸10mg、有机锗9800ppm，及微量元素等其它成分，它们具有强烈的生理活性，单独或协同作用。

具有较强抗肿瘤作用的灵芝多糖的基本结构和三萜类分子式见“破壁灵芝孢子”部分。

Contained in each 100mg Zhong Ke Ganoderma Spore Oil, there are 37mg triterpenes, 11mg polyoses, 22mg nucleosides 10mg fatty acid and 9980ppm organic germanium and other ingredients like trace elements, with acute Biological activity, which act in single or jointly.

For the basic structure and the triterpenes' molecular equation of Ganoderma polyose with strong anti-tumor Activity Spore Oil, please refer to the Ganoderma Spore with Broken Sporoderm.

二、抑瘤机制 Anti-tumour Mechanism

灵芝孢子油作为新型的具有抑制肿瘤作用的生物调节剂（BRM），其抑瘤机制与破壁灵芝孢子基本相同，但由于三萜类的大量存在，灵芝孢子油对肿瘤细胞的毒杀作用更强，减轻癌痛的作用更明显。

以下为部分实验数据：

肝癌AH-3、AH-7974、AH-66F抑瘤率为84.1~91.6%；

腹水型肝HEPS癌抑瘤率为67.8~78.4%；

痛阈值（机体抗痛能力）提高84倍。

As the new biomodulator with anti-tumour activity, the anti-tumour mechanism of Ganoderma Spore Oil is similar to that of Ganoderma Spore with Broken Sporoderm, but Ganoderma Spore Oil can more effectively kill the tumour cells and alleviate the tumour pain as there are large number of triterpenes existed.

The testing information is as follow:

Cancer inhibiting rate for liver cancer AH-3, AH-7974 and AH-66F: 84.1% - 91.6%;

Cancer inhibiting rate for ascitic liver HEPS cancer: 67.8% - 78.4%;

Pain Threshold (Pain Resisting Capability) increases 84 times.

三、毒理学 Toxicology

1、急性经口毒性实验：雌雄小鼠LD₅₀均大于15.8g/kg。

2、Ames试验：对标准测试菌TA97a、TA98、TA100和TA102，平板掺入法，剂量达5000 ug/皿，加及不加S₉，均未检出明显的诱变活性。

3、小鼠骨髓嗜多染红细胞微核试验：剂量达10g/kg体重，雌雄小鼠均未检出对骨髓嗜多染红细胞的诱变活性。

4、小鼠睾丸初级精母细胞染色体的诱变活性：剂量达10g/kg体重，未检出对雄性小鼠睾丸初级精母细胞染色体的诱变活性。

结论：中科灵芝孢子油属无毒级。

1. Acute Peroral Toxicological Test: female/male mouse LD₅₀ > 15.8g/kg. 2. Ames Test: for the standard testing microbe TA97a, TA98, TA100 and TA102, via Plate Infiltration Method, dosage of 5,000ug/vessel, with or without S₉, no apparent mutagenic activity was found.

3. Myeloid Rubricyte Micronucleolus Test on Mouse: with dosage of 10g/kg, no mutagenic activity to rubricyte was found on both male and female mouse. 4. Mutagenic Activity to Initial Spermatocyte Chromosome of Testicle of Mouse: with dosage of 10g/gm, no Mutagenic Activity to Initial Spermatocyte Chromosome of Testicle was discovered on female mouse.

Conclusion: Zhong Ke Ganoderma Spore Oil is a toxicity-free product

用法与用量 Usage and Dpsage:

名称	情况	用法	因肿瘤引起的疼痛	肿瘤恢复期
灵芝孢子油软胶囊	1、不能进行手术、放疗、化疗； 2、确诊后到手术（或直接化疗）前； 3、放、化疗前，放、化疗中白细胞/血色素异常； 4、进入晚期（M）	1、手术后到放、化前； 2、放、化疗中； 3、放、化疗结束后半月内；1、2、3、各项化验指标均正常	每天4粒，每6小时1粒，空腹服用	每日1粒，空腹服用

Condition	1. Not possible to conduct operation, radiotherapy and chemotherapy; 2. After diagnosing and before operation (direct therapy or Chemotherapy); 3. Before radiotherapy and chemotherapy; abnormal condition of leukocyte and hematopoiesis during radiotherapy and chemotherapy; 4. In late phase (M).	1. After operation, before radiotherapy and chemotherapy; 2. During chemotherapy and radiotherapy; 3. In half a month after hemotherapy and radiotherapy; and the testing indices are normal in Test 1, 2 and 3.	Pains caused by tumour.	Recovery period of tumour patients.
Name				
Ganoderma Spore Oil Soft Capsule	Take 3 times a day, 1 cap. Each time before meal.	Take 2 times a day, 1 cap. Each time before meal.	Take 4 cap. a day, i.e., 1 cap./6 hours before meal.	1 cap. per day before meal.

灵芝孢子油的特点 Feature of Ganoderma Spore Oil

与破壁灵芝孢子相比，灵芝孢子油服用更方便，作用更明显：

- 1、增加了量效比。由于灵芝孢子油浓缩了20倍重量的灵芝孢子粉的有效成分，可以认为其功效成分是同重量灵芝孢子的20倍。这样，肿瘤患者的服用量将大幅度减少，减轻了病人大量服用的心理负担，同时，服用效果却得到增强。
- 2、服用更方便。由于采用了先进的软胶囊技术，胶囊含在口中即可化掉，病人可以吞服、含服，对于吞咽困难的病人，可以打开胶囊一端，挤入病人口中服用。
- 3、经济上与破壁灵芝孢子相差不大。1粒“中科”灵芝孢子油软胶囊(500mg)在价格上相当于10粒“中科”灵芝孢子胶囊(150mg)，但其有效成分的净含量是1粒“中科”灵芝孢子胶囊的40~60倍，尤其对于放、化疗和晚期、疼痛的病人，相同的费用却能起到更大的作用。

Compared with Ganoderma Spore with Broken Sporoderm, Ganoderma Spore Oil is more convenient to medicate and its effect is more obvious:

1. Quantity-effect ratio increased: Because Ganoderma Spore Oil concentrates the active ingredients of Ganoderma Spore with Broken Sporoderm of 20 times of its weight, it can be considered that its activity is 20 times of the Ganoderma Spore with Broken Sporoderm with the same weight. So the dosage for the patients is largely decreased and the fear for taking large quantity of medicine can be decreased, when its effects are improved.
2. More convenient to take: Adopting the advanced soft capsule technology, able to melt in mouth, the capsule can be medicated by oral or keeping in mouth. For the patients who are difficult to swallow, open one end of the capsule to squeeze it into the mouth of the patients.
3. The price of the oil similar to the Ganoderma Spore with Broken Sporoderm: The price of one capsule of Zhong Ke Ganoderma Spore Oil soft capsule (500mg) is similar to the price of 10 capsule of Zhong Ke Ganoderma Spore with Broken Sporoderm (150mg), but its content of active ingredients is 40-60 times of that of one capsule of Zhong Ke Ganoderma Spore with Broken Sporoderm. Especially for the patients after chemotherapy and radiotherapy, in late phase and with tumour ache, the effect would be better with the same expense.

CO₂超临界萃取技术 CO₂ Super-critical Extracting Technology

所谓CO₂超临界萃取技术，是在一定温度和压力条件下，通过超临界状态的CO₂萃取人们需要的物质的有效成分。大家知道，物质通常有三态：即固态、液态、气态。但在特殊条件下，许多物态转化。处于转化过程中的物质兼具两态，这就是超临界状态。CO₂的超临界状态即由气体转化为液体，被萃取物在这种状态下被析离，当CO₂还原为气态并完全挥发后，被析离的物质成分就完整地提取了出来，而杂质和无效成分就被分离出去。由于CO₂无毒副作用，能完全挥发无残留，被萃取的有效成分特别纯净，特别全面，是当今萃取手段中最先进的技术。这项技术约在80年代中期由日本专家首先发明，我国列入“八五”国家科技攻关计划，在国际上，每三年要召开一次超临界流体学术会议，我国已于1996年和1998年召开了两次全国学术会议，由此可见这项技术在今天的重要性和跨世纪的先进价值。1999年底，中国科学院采用超临界CO₂萃取灵芝孢子油并取得成功。

由于萃取灵芝孢子油首先要对灵芝孢子在常温下进行破壁，而萃取不同物质又有特殊的强度、压力、流程等工艺要求，使“中科”灵芝孢子油的提纯技术在短时间内难以超越和模仿。

CO₂ Super-critical Extracting Technology is used to extract the effective ingredients needed by people with super-critical CO₂ under certain temperature and pressure. It is known that there are three states for substances generally, solid, liquid and gas. But in special circumstances, there are a lot of State Alterations existed. The substances has the feature of two states at the same time during alteration from one state to another state, it is called super-critical state. The super-critical state of CO₂, under which the extracted substance is separated, is the state changing from gas state to liquid state. The active ingredients in substances are separated completely but the foreign articles and in-active ingredients are excluded after CO₂ is restored to gas and volatiles. The non-toxic CO₂ can Volatile completely and the extracted active ingredients especially pure and overall, so it is the most advanced extracting technology in modern society. This technology was discovered first by the experts in Japan in mid-1980s, which was listed among the state 8th five-year technological pioneer plan. An international super-critical technology seminar is held every three years in the world and two nationwide super-critical technology seminars were held in China in 1996 and 1998 respectively. Ganoderma Spore Oil was successfully extracted with CO₂ super-critical technology in China Academy of Sciences at the end of 1999.

Because it has to break the sporoderm first under normal temperature to extract Ganoderma Spore Oil, and there are special processing requirements for intensity, pressure and process to extract different substance, the extracting technology of Zhong Ke Ganoderma Spore Oil is difficult to be exceeded and copied in a short period of time.

破壁是萃取灵芝孢子油的另一关键技术

Spore Wall Breaking Is Another Key Technology

中国科学院有关单位采用CO₂超临界萃取技术提取灵芝孢子油时发现，用未破壁的灵芝孢子粉作原料几乎没有提取量，加长时间，调整工艺，提高萃取压力后提取率也仅有0.2%左右，只有在研制成功灵芝孢子的现代物理破壁技术之后，采用破壁的灵芝孢子粉作原料，萃取率才提高上来，而且破壁率越高，萃取率越高。采用破壁率大于95%的“中科”灵芝孢子粉，每100公斤可提取5公斤左右的纯灵芝孢子油。因此，可以认为灵芝孢子的破壁技术是提纯灵芝孢子有效成分技术中的另一关键技术。

When the relative units of China Academy of Sciences extracted Ganoderma Spore Oil via CO₂ super-critical technology, they found that no Ganoderma Spore Oil was extracted using Ganoderma Spore powder that was not broken Sporoderm as material, and the extracting rate would rise to about 0.2% when the time was lengthened, process adjusted and extracting pressure raised. The extracting rate rose only when adopting the Sporoderm-broken materials, which was made via the modern physical Sporoderm-broken technology for Ganoderma Spore, as raw material, and the extracting rate would be higher when the rate of Sporoderm breakage is higher. Adopting Zhong Ke Ganoderma Spore powder with over 95% Sporoderm-broken rate, about 5kg pure Ganoderma Spore Oil can be extracted in each 100 kg Ganoderma Spore powder. Therefore, it can be regarded that Sporoderm-broken technology is another key technology for the active ingredient extracting of Ganoderma Spore Oil.

附录 Appendix

我科学家研究发现灵芝孢子的抗病“主力”（摘录）

新华社北京2001年3月12日晚报专电 被列为国家产学研重大项目的灵芝孢子研究取得重要突破。经我国科学家多年研究发现，灵芝孢子的真正精华是蕴藏在灵芝孢子内的脂质活性物质，医学研究证明，它是灵芝能发挥保健、治病功效的“主力”。

在电镜下，直径仅6微米（1微米为千分之一毫米）的灵芝孢子呈椭圆卵形，却有两层坚韧的孢壁，在两层孢壁之间还有间隔排列的圆柱形管腔，其孢壁又是由几丁质、纤维素、树脂、多糖等组成，灵芝孢壁的这种巧夺天工的构造使灵芝孢子具有极强的牢固性，它是灵芝在长期的进化过程中形成的有效保护孢腔内物质的遗传特性，也是灵芝孢子之所以难于破壁和未破壁的灵芝孢子难以被人体充分吸收的重要原因。

用超临界二氧化碳流体萃取技术，将全破碎的孢壁及壁内的脂质活性物质分离。这种脂质活性物质是灵芝孢子发挥保健和治病功效的“主力”。这是灵芝研究及应用上的一个重要发现及突破。动物实验表明，这种脂质活性物质的抑瘤率平均可达91.6%。而传统认为灵芝孢子起主要治病作用的灵芝多糖的抑瘤率仅为

Scientists in China Discovered the Active Ingredients in Ganoderma Spore (Excerpt)

From of Evening Post of Xing Hua News Agency on Mar. 12, 2001: A Breakthrough in Ganoderma Spore Study Project listed in State Production, Academy and Research Key Projects. After years of study, the scientists in China found that the real essence in Ganoderma was the lipid active ingredients, which has been proved as the main ingredients in Ganoderma to protect health and cure disease after medical research.

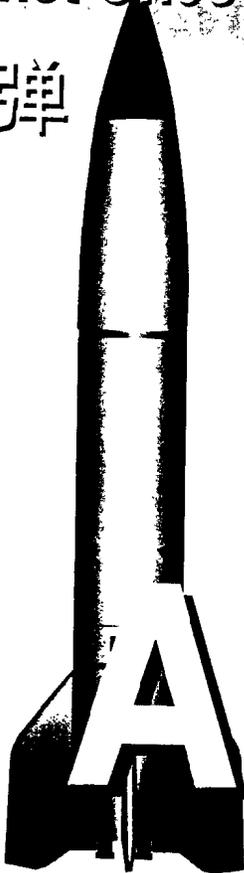
Under microscope, elliptical with a diameter of 60m, Ganoderma Spore has two layers firm and tenacious sporoderm, between which there are cylindered cavity with radial arrangement, which consist of chitin, cellulose, resin and polyoses. It is this incredible structure of Ganoderma Spore Oil, a hereditary feature formed to protect the effective ingredients in Ganoderma Spore's cavity during the evolution process, makes Ganoderma Spore Oil solid, and becomes the important reason why the sporoderm of Ganoderma Spore is so difficult to break and the Ganoderma Spore with un-broken sporoderm is difficult to be absorbed fully by human.

The super-critical CO₂ liquid extracting technology can be adopted to separate the totally fragmented sporoderm with the lipid active ingredients inside sporoderm, which is the main substance in Ganoderma Spore to protect health and cure disease. This is an important discovery and breakthrough in the study and application of Ganoderma. The animal test evidenced that the average tumour-inhibiting rate of this lipid active substance reached to 91.6%, while the tumour-inhibiting rate of Ganoderma Polyose, considered as the most active ingredients of Ganoderma Spore before, is only 40~50%.

The Biological Missile Against Oncogene

瞄准癌基因的生物导弹

中科院



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中科 AT ZHONGKE® AT Capsule

中科 AT (中文名“爱特”), 是用人体基因中的两个碱基 A 和 T 命名的生物制剂, 曾被欧洲报导为“瞄准癌基因的生物导弹”。

癌细胞是由正常细胞突变而来的, 这些突变主要发生在三类细胞基因上, 它们是癌基因 (ONCOGENE)、抑癌基因 (TUMOR SUPPRESSOR GENE) 和 DNA 修复基因 (DNA REPAIR GENE)。癌基因和抑癌基因 (又称抗癌基因, ANTI-ONCOGENE) 是生理学功能相反的基因, 是肿瘤细胞在增殖、生长、分化、凋亡等生命过程中正和负两类调控信号。癌基因的活化和抑癌基因的失活导致突变产生癌细胞, 并促进癌细胞的生长、繁殖。

抑癌基因 P₅₃ 的缺失或突变已被证实是许多肿瘤发生的原因之一。自 1989 年以来, 人们在越来越多的不同类型的肿瘤中发现了 P₅₃ 基因的突变。其中包括胃癌、肺癌、肝癌、结肠癌、膀胱癌、乳腺癌、头颈部鳞状细胞癌、前列腺癌、胶质细胞瘤、软组织肉瘤、骨肉瘤、淋巴造血系统肿瘤等, 其突变形式可表现为点突变, 缺失突变、插入突变、移码突变、基因重排等, 如肺癌、肝癌 G → T 的转变, 结肠癌 GC → AT 的转变, 等等。

同时发现, P₅₃ 在细胞对 DNA 损伤所发生的应答过程中起关键性作用, 含野生型 P₅₃ 的细胞, 在 DNA 受到损伤时可使细胞停止于 G1 期, 在 DNA 开始合成前进行损伤的修复。而缺乏 P₅₃ 野生型功能的细胞则不能阻滞于 G1 期来修复损伤的 DNA, 从而导致细胞 DNA 的错误复制, 细胞进一步恶化。这说明 P₅₃ 的失活可促使肿瘤细胞进一步出现基因组的不稳定性, 促进肿瘤细胞进一步向恶性转化。

因此, 阻止细胞 P₅₃ 的突变具有多方面的意义:

- 1、阻止肿瘤细胞的进一步恶化;
- 2、阻止肿瘤周边细胞的基因变异, 从而控制肿瘤的扩张。
- 3、制约癌基因发出的促生长繁殖信号, 诱导肿瘤细胞凋亡, 启动其“自生自灭”程序。

中科 AT (爱特) 可及时阻止 P₅₃ 基因突变, 增加细胞中的野生型 P₅₃ 基因。它由中国科学院和新加坡皇家医药研究中心, 共同研制, 采用姬松茸, 蝙蝠蛾被孢霉、灵芝孢子、虫草、云芝提取物等自然物质配方, 对人体无副作用。

Zhongke AT, which is a kind of biology preparation named with two bases-A and U in body gene, it was once reported as "biological missile against oncogene".

Cancer cells are formed because of the normal cells' mutation. The mainly three kinds of mutation cells are as follows: Oncogene, tumor suppressor gene and DNA repair gene.

Oncogene and tumor suppressor gene (also called antioncogene) are the opposite genes of physiology function, two positive and negative regulating singles during the time of reproduction, growth, differentiation and fading of tumour cells. The activation of oncogene and inactivation of tumor suppressor gene lead to mutation and form cancer cells, and promote the growth and reproduction of cancer cells.

Deficiency and mutation of tumor suppressor gene P₅₃ have been confirmed to be one of the reasons of causing many tumours. People have found the mutation of P₅₃ gene among more and more different tumors since 1989, including carcinoma of stomach, lung, liver, colon, bladder, breast, scaly cells in head and neck cancer and prostate. Besides it also includes collencyte tumor, tumor in soft tissue, tumor in bone and tumour in lymph blood-producing system, etc. Forms of mutation can be different as point mutation, deletion mutation, insertional mutation, sign mutation and gene recombination, etc. For example, carcinoma of lung, transformation of carcinoma of liver G-T and transformation of carcinoma of colon GC-AT, etc.

It is discovered that P₅₃ plays a key role during the time of cell to DNA damage response. The cells that contains wild type P₅₃ will be blocked down at G1 phase at the time when DNA is damaged, and begins reparation before DNA starts to duplicate, so as to avoid the replication mistake of cell DNA, and deteriorate cells. It proves that the inactivation of P₅₃ can urge tumour cell to further appear lability of geonom, and promote tumor cell to transform to malignancy.

Therefore, it is very important to inhibit the mutation of cell P₅₃:

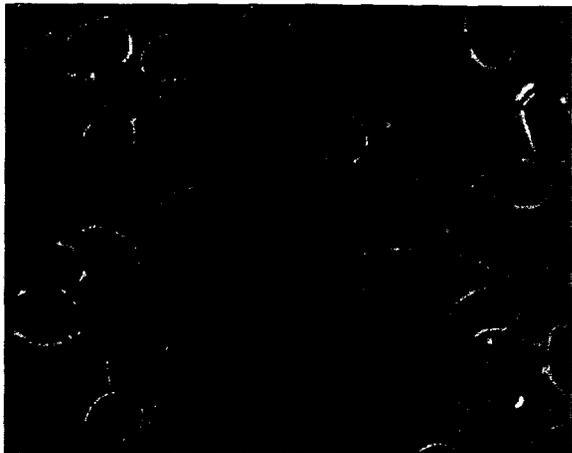
1. Inhibit tumour cell to deteriorate further.

2. Inhibit genovariation around tumour so as to control the expansion of tumour.

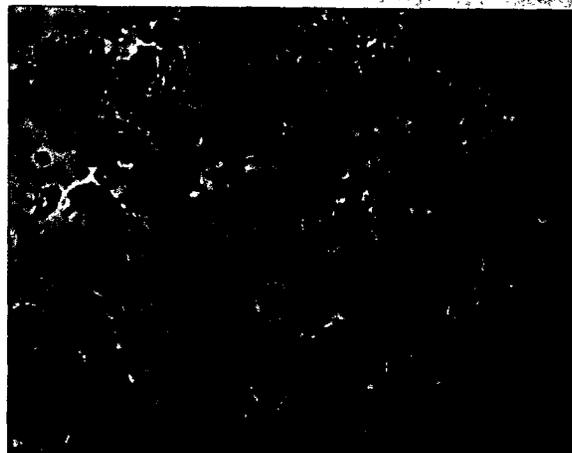
3. Restrict reproduction signal of growth promotion delivered by oncogene, guide tumour cell to fade, and start up the program of self-generation and suicide.

Zhongke AT can duly inhibit the mutation of P53, add wild-type P53 gene in cell. It was jointly researched by the Chinese Academy Of Science, Singapore Chinese Medicine Research Center. It contains ichuomol, bat moth mold, ganoderma, cordycepic,

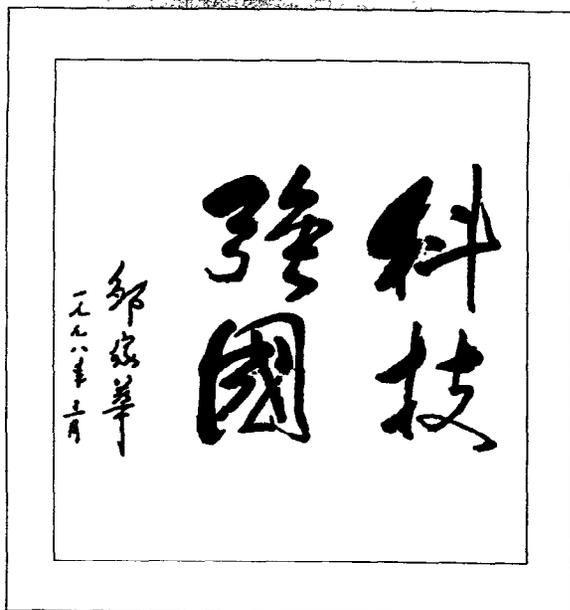
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 Production and Sales of Zhongke Ganoderma Lucidum Spore Have Been Approved by the Ministry of Health



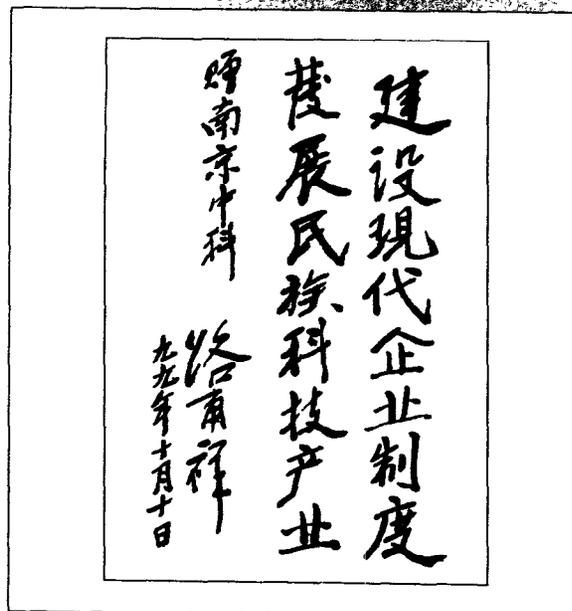
灵芝孢子粉
 Ganoderma Lucidum Spore



“中科”破壁灵芝孢子
 ZHONGKE Shell-broken Ganoderma Lucidum Spore



全国人大邹家华副委员长为“中科”题词
 Zou Jiahua, Vice Chairman of NPC Inscribed for Zhongke.



中国科学院院长路甬祥为“中科”题词
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<p><u>GURU Fully Sporoderm-broken Pure Ganoderma Sporo- pollen Capsule</u></p>
<p><u>Ganoderma Tea Series</u></p>



GURU Fully Sporoderm-broken Pure Ganoderma Sporo-pollen Capsule

This product has authenticated for health product by FDA of USA in 1999(No.95s-0316)and for health food by the Ministry of Chinese National Public Health(WEI SHI JIAN ZI

Food Engineering research Center
 食品工程研究中心
 OF State Education



2000 No.0393)and has been developed the procedure for medicine.All tests showed that our prodrct had no toxic or sied effect.

Having founded the theory of germination activating, experts from Food Engineering Research Center of State Education Ministry and Zhongshan University have carefully selected fine Ganoderma lucidum strains by cell fusion methods, and set up a production base for Ganoderma lucidum spores by wood culture in 1,100m mountains. The Ganoderma spore in dormancy is processed by germination activating, sporoderm softening and breaking with enzyme engineering and freeze drying technology, which can effectively retain the active materials that can promote and activate the body's stable response reaction and enhance immunity, so that the fully sporoderm broken Ganoderma spore shows much more efficient physiological activity than ordinary Ganoderma spore.

This product has passed the strict examination and test by FDA of the USA and has been authenticated for health product by FDA. This product has been submitted to Public Health Ministry of China for Health Food authentication and has been developed the procedure for medicine.

In accordance with national and international specified standards, this product doesn't have any toxic or side effect.

It was reported that the mechanism of antitumor is due to the germination activated Ganoderma spore could promote and activate the body's stable response reaction to regulate the hormones and receptors in metabolism, neuroendocrine and immune systems, hence to support the healthy energy and strengthen the body resistance, prevent cancer hepatitis and other diseases.

Germination activated Ganoderma spore could enhance immunity, regulate cardiohaemal system, improve respiratory and digestive system, build up vital energy, calm nerves, show antitumour, detoxification and liver protection effect, then have good effects on pains, insomnia, anorexia, fatigue, white cells reducing and other symptoms caused by chemotherapy and radiotherapy.

Product's features: germination activated, high purity, high active, fully sporoderm-broken, immunity enhancing and anti-tumor effect.

Food Engineering Research Center of State Education Ministry of China and its attachment, Guangzhou Green Food Engineering Co., have set up a bioprocessing industrialization base in Guangzhou for germination activated Ganoderma lucidum spore powder capsule, and a raw materials base for fine Ganoderma lucidum spores in 1,100m mountains in Fujian. GURU Ganoderma Spore Powder Capsule have been put into domestic and overseas market and have won a high reputation.

Ganoderma Tea Series

After thousands of experiments, the wonderful Ganoderma tea products, developed by biologists and nutrition experts in Food Engineering Research Center of State Education Ministry and zhongshan University, was prepared by updated

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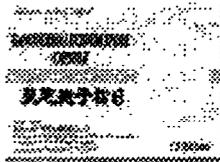
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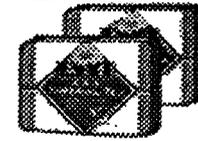
NO: C234
NAME : Ganoderma Lucidum Spore Capsule
PRICE : \$16.80

INGREDIENT : Ganoderma Lucidum Spore, Cordyceps Sinensis Mycelia

FUNCTION : Ganoderma lucidum (GL) is a precious rare Chinese materia medica. It is also a well-known herb to every household just as a legendary saying: "it is a herbal elixir that can raise the dead". Although it is merely a fairy tale, we can imagine its excellent efficacy.

GL Spore is the semen of the GL that contains the essence of GL. Its efficacy exceeds far more than that of GL.. Cordyceps sinensis (CS), a famous tonic, is also a precious Chinese materia medica. The CS mycelia is the natural fermented and cultured product. Its ingredients and efficacy are identical with that of CS and it is a

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substitute of natural CS.

The combination of GL and CS can regulate the body function, promote metabolism and enhance the immunity. Ganoderma Lucidum Spore Capsule is made of GL Spore essence and CS mycelia, having a beneficial action to those people who are suffered in tumor or in lower immune function.

USAGE & DOSAGE : Used as a herbal supplement, orally taken, 3-5 capsules each time, three times a day.

SPECIFICATION : 20 cap./bx .

STORAGE : Stored in a cool and dry place.

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中国食用菌技术开发有限公司

China Edible Fungi Technology Development Co.,Ltd

Lingzhi

※The King of Lingzhi§and His ※Zihang Ganoderma Lucidum Spore Powder§

AboutUs

((About 30 years ago, Mr. Pan Zihang was demobilized from the army. During the Ten-year Turmoil (also called the Cultural Revolution in China from 1966 to 1976), he missed the chances of promotion in the army because his mother was regarded as a ※landlord§ at that time. Having left the army, he had to make a living by himself. Mr. Pan Zihang initiated his research on Lingzhi in his efforts to help cure his wife *s illnesses. Pan *s wife, Qian Xiaofeng, suffered from serious bronchitis and TB, which often made her spit blood. X-rays revealed two 1.5-cm-diameter holes in her lungs. The couple *s efforts to seek treatment were all in vain. Subsequently, Pan consulted an expert in traditional Chinese medicine, who gave him the following prescription: ※Boil Lingzhi and tremella, adding crystal sugar. If your wife drinks it twice a day: in the morning before breakfast and in the evening after supper, it can surely cure her problems.§ Pan followed the instruction, and three months later, his wife recovered, while X-rays showed that the cavities had disappeared. Pan then began to realize the medical value of Lingzhi. People said, ※Lingzhi saved his wife *s life, hence his enthusiasm about it.§

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((Years later, Pan Zihang successfully cultivated a kind of Lingzhi with his own special technique. He named it ※Zihang Lingzhi§. Furthermore, to his surprise and great joy, Pan discovered in the process of cultivation that the mature Lingzhi sent out red, cloudy spore powder, which can be collected and refined through scientific methods and applied to patients with quick results. Tests have revealed that the spore powder is rich in polysaccharides, glycosides, protein and amino acids, some of which are rare in grain and vegetables and while essential for growth can not be produced by the human body. The spore powder is the essence of Lingzhi. Pan named it ※Zihang Ganoderma Lucidum Spore Powder§.

((In the appraisal meeting sponsored by China Preventative Medicine Association, more than ten senior experts held an unanimous view that ※Zihang Ganoderma Lucidum Spore Powder is a kind of pure natural powder saprophyte material released by mature Zihang Lingzhi cultivated with special technique. There is no poisonous reaction after it is taken with a dosage of 48g for every kilogram of body weight. It is really a valuable innovation based on the application of Lingzhi and is a significant medical discovery.§ Mr. Pan Zihang is the first man who discovered ganoderma lucidum (spore (powder (in (China.

((With ※Zihang Lingzhi§ and ※Zihang Ganoderma Lucidum Spore Powder§ as his main products, Mr. Pan Zihang *s business develops quickly. In July, 1989, with special permission from the State Administration for Industry and Commerce of the P.R.C., he established China Edible Fungi Technology Development Co. Ltd. (the first and the only private company ever permitted to use the word ※China§ in the name of the company) in the city of Maanshan, Anhui Province. In 1994, his company moved to No. 18 Fuxing Road, Beijing with a registered capital of 3.6 million U.S. dollars. Now as a member of the executive council of China High-Technology Industrialization Research Association and Chairman of the Board and General Manager of China Edible Fungi Technology Development Co. Ltd., Mr. Pan owns a large enterprise group, which includes China Edible Fungi Technology Development Co. Ltd., Shenzhou Zihang Pharmaceutical Co. Ltd., Beijing Zihang Ganoderma Liquor Co. Ltd., Nanjing Zihang Health Products Corporation, Liaoning Provincial Zihang Medicines and Health Products Sales Center and other companies. Because of his outstanding position in the development of Lingzhi industry in China, Mr. Pan Zihang is called ※the King of Lingzhi§ by Xinhua News Agency, China News Agency, the People *s Daily and other

news media.

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- Foods

Ultra-fine High Broken Spirulina Powder

Spirulina is a kind of green basic food which is internationally acknowledged as nutritious and nutritive balanced. It is functional on angiocardiopathy, diabetes, cancer, hypertension, hyperlipemia, anemia, gastropathy and other diseases. Adopting advanced low temperature physical comminution technology to completely break up spirulina's cell wall, we can manufacture products whose particle-size are all less than 5 μ m for the fully absorption of body. the nourishment of 1g of spirulina = total nourishment of 1000g of all of kinds of vegetables

Ultra-fine High Broken Pollen

Flower powder is the sperm of plants. It contains not only genetic information but also all the nutritive materials new lives need. There are also vitamin A,B,C,D,E,K,..., various amino acids, trace elements, bioactivator and other elements increasing body immunity. The materials are pure natural flower powder from northwest plateau without any pollution. Adopting advanced low temperature physical comminution technology without any additive to preserve the efficient elements and the cell breaking-up rate is $\geq 99.5\%$. The product does good to people's immunity and beauty.

Ultra-fine Tea Powder

Adopting advanced pure physical micron ultra technology, we comminute quality tea powder into less than 10 μ m, so that the globulin, vitamin A.D.E.K and mineral nutrition and other nutritional ingredients can be absorbed by bodies. Ultra-fine red and green tea powder, accompanied by cane sugar, edible essence, spirulina or milk powder, will help you decrease blood-fat, blood sugar and increase immunity. The product is widely used in the fields of foods, drinking, cosmetic

Clean Night Sweat

The product is Chinese traditional medicine specially for night sweat and health protection of infants and teenagers. It is sweet for children to take.

- **Medicinal Materials**

Ultra-fine High Broken Ganoderma Lucidum Spore Pollen Powder

Ganoderma Lucidum spore pollen, the essence of Ganoderma Lucidum, is released when Ganoderma Lucidum matures. It is a kind of grey powder. It contains polyoses, peptide, triterpenes, etc.. It not only can help to increase immunity, anti-anoxia, anti-senility, anti-cancer, but also is effective on malignant tumor, coronary disease, chronic bronchitis, hepatitis, leukopenia, hyp immunity and other diseases. We choose quality ganoderma lucidum seed's spore powder and adopt low temperature physical comminution technology, the breaking-up ratio beyond 99% and particle size averaging out to 1.5 μ m. The active principle can all be absorbed by body. We have cooperated with Hongkong Leiyunshang Pharm Corp. and our products sell well in international market.

Ultra-fine Ganoderma Lucidum Powder

We adopt advanced low temperature physical comminution technology to make the product less than 5 μ m, so, unlike traditional cooking method, the product can be fully absorbed by body. The product can help to increase immunity and inhibit enteric tumor.

Jisongrong(power)

It is originated in Brazil. It is a kind of fungus, and its pileus' diameter is 6-11 cm long and is of the shape of half ball or expands evenly. Besides that it is edible, it also has potential medicine effect. The amylose protein extracted from it has the nature of anti-tumour. Dry power is yellow in color. Retail price: RMB 500/kg; Package: 2kg/sack (tinfoil-plastic vacuumized).

Aweto Mycelium (power)

It uses aweto epiphyte extracted from natural aweto, and is artificially cultivated with modern biology engineering. It contains many kinds of amino acid. Its amylose percentage is above 12%. It has the medicine function of lowering glycemia and blood pressure, anti-inflammation, composure, etc. The dry power is brown, and have a delicious taste. Retail price: RMB 400/kg; Package: 2kg/sack (tinfoil-plastic vacuumized).

Hedgehog Fungus (power)

It is one of the famous edible funguses. It has faint scent, a delicious taste, and is rich in nourishment. It contains many kinds of amino acid, seven of which are necessary for human beings. Chinese traditional medical theory believes that hedgehog fungus has an even nature and a delicious taste, and that it is beneficial for the five internal organs

and digestion. It has good curative effect for neurasthenic, gastric ulcer, and chronic gastricism. Amylose and multi-peptide discovered recently have good effect of anti-cancer. Retail price: RMB 300/kg; Package: 2kg/sack (tinfoil-plastic vacuumized).

Yunzhi Extract Powder

The effective content is above 42%, and the percentage of heavy metal (lead, arsenic, hydrargyrum)(mg/kg) is below the state standard. The dry power is puce. Retail price: RMB 560/kg; Package: 2kg/sack (tinfoil-plastic vacuumized).

Medlar (power)

We choose first-class Ninxia medlar and powered it ultra-finely with high-tech so that it can be completely absorbed by your body. When medlar is eaten with water traditionally, many effective content which can not dissolve in water is wasted. So taking this product can have a much better effect than in traditional way and can make you more healthy. Functions: beneficial for kidneys, lungs, livers, eyes. Retail price: RMB 150/kg; Package: 2kg/sack (tinfoil-plastic vacuumized).