

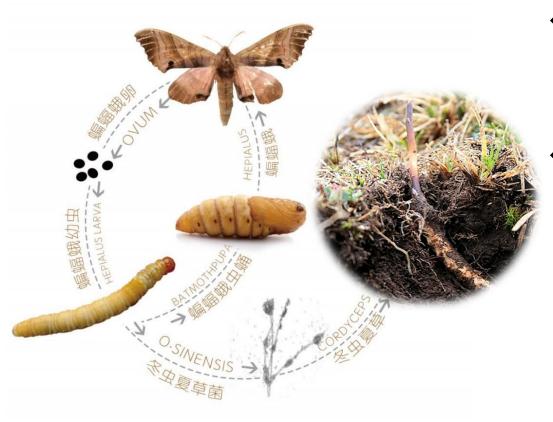
### TCM BIOTECH INTERNATIONAL CORP.

**泰宗生物科技股份有限公司** 

The World Class Expert of Cordyceps

# Cordyceps sinensis

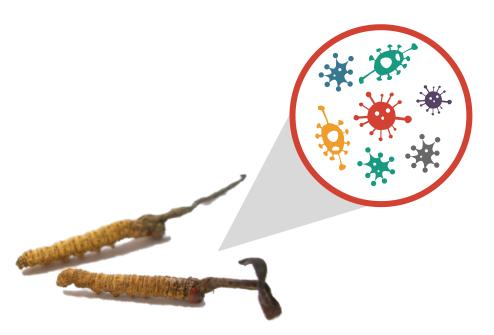




- ◆ Named as "'winter worm, summer grass" in Chinese literally, *Cordyceps sinensis* is neither worm nor grass. Instead, it is a larva-fungus complex.
- More than 400 Cordyceps genera have been discovered worldwide, but the only one ever specified by traditional Chinese medicine scholars is the fungus of <u>Cordyceps sinensis</u> (Berk.) Sacc parasitizing the larva of Bat Moth (*Hepialus armoricanus* Oberthur).

## Cultured Mycelia of Cordyceps sinensis-LivPhcD







### Isolating /purifying fungal strains

All varieties of strains from the stroma and sclerotium Cordyceps sinensis were obtained after proliferation of cells through the sterilized-isolating technique.



## Identifying fungal strains

The isolated strains were identified as the authentic Cordyceps sinensis by the Research Center on Entomogenous Fungi, Mycological Society of China.



**Identification report** 

#### **Effective strains**

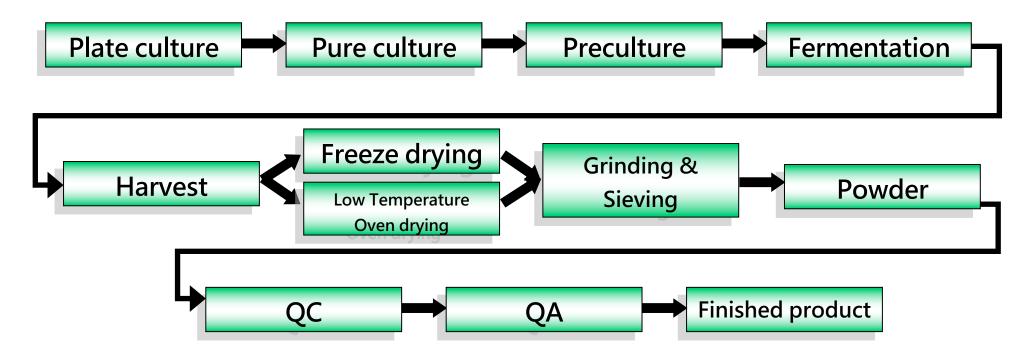
Samsoniella hepiali : LivPhcD

## **Production Footsteps**



### Proprietary submerged fermentation and production techniques

TCM Biotech 's researchers collect and analyze the fermentative broth of various stages to find out the best culturing conditions and harvest timing.



## Exclusive fermentation technology and equipment





Automatic vertical semi-airlift hybrid reactor



International standard quality control



Strain preservation



Automatic monitoring system

# LivPhcD VS Other cordyceps mycelium



	Cordyceps mycelium produced by TCM	Other cordyceps mycelium	Cordyceps militaris often mistaken for Cordyceps sinensis
	LivPhcD		
Bioactive ingredient concentration high		low	low
health benefits	<ul><li>Promote health</li><li>Boost immunity</li><li>Liver protection</li></ul>	Promote health	Promote health
patent	A number of functions and process patents	Unknown	Unknown

### **Patents**



#### 

#### (12) United States Patent Wang et al.

(54) METHODS FOR MAKING AND

(75) Inventors: Ya-Chun Wang, Yanshui Township, Tainan County (TW); Wang-Sheng Ko, Taichung (TW); Chih-Cheng Chang,

(73) Assignce: TCM Biotech International Corp.,

Prior Publication Data

US 2010/0021426 A1 Jan. 28, 2010

#### Related U.S. Application Data

(60) Continuation-in-part of application No. 12/411,940, filed on Mar. 26, 2009, new abandoned, which is a continuation of application No. 12/003,736, filed on Dec. 31, 2007, now abandoned, which is a division of application No. 10/755,468, filed on Jan. 13, 2004, now abandoned.

#### Foreign Application Priority Data

	Oct. 3, 2003	(TW)		92127864 A
(51)	Int. Cl. 461K 36/06		(2006.01)	
(52)	U.S. CL		424/194	5.15: 424/115

See application file for complete search history.

ILS PATENT DOCUMENTS

6.126.942	Α	10/2000	Yang	
6.271.003	BI	8/2001	Hsen et al.	
6.737.065	B2	5/2004	Song et al.	
6,921,634	B2	7/2005	Lemon et al.	
2003/0095982		5/2003		
2004/0137080	AI*	7/2004	Cremisi	424/7
2006/0094689	A1	5/2006	Kristiansen et al.	
2007/0004022	AI	1/2007	Shea	
2008/0299645	Al	12/2008	Cleaver et al.	

FOREIGN PATENT DOCUMENTS

CN		* 12/1997
CN	ZL99106135.7	5/2003
CN	ZI.200310101281.1	9/2006
TW	192356	12/2003

(10) Patent No.: US 8,722,056 B2 (45) Date of Patent:

TW 258373 7/2006 WO PCI/CN98 00258 5/1999 WO WO9921961 A1 ° 5/1999 OTHER PUBLICATIONS

Batev R. et al., "Double blind placebo controlled prospective trial Bary, F. et al., "Double blind placebo controlled prospective trial to investigatable effect of Corrlegory sissions, Supplementation in main-maining ancient, depression and fulge associated with chronic legistric ("America Observations and maining associated with chronic legistric ("America Observation Conference in Lidons, Portugal, Feb. 7-8, 2022, administration of the automation of the automation of the formation of the fore

200, 597-607 (2003).
Cohen M. R. et al. The Hopseline CHdp Book, Chapter V. Woodschook M. et al. The Hopseline CHdp Book, Chapter V. Woodschook M. et al. The Hopseline CHdp Book, Chapter V. Woodschook M. et al. Chapter Chdp M. et al. Chdp M. e inemoty deficit in rats; 'Bot. Plants Bull., 2A(3):1126-29 (2004).
Kin G. et al., "Woter central of Condyceps adiplants enhances maturation of nursine bene marrow-derived dendrific cells in vitro." Bot. Plants. Bull., 262; 384-60 (2004).
Ko W., "Supplement therapeutic dendrific cells in vitro." Bot. For popularity of the condition of the condit

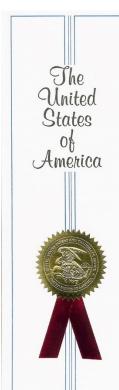
preparation in treatment of twee camage, 995HKU05111007 (1995). Koh J. et al., "Activation of macrophages and the intestinal immun-

system by an orally administered decoction from cultured mycefa of Comfyceps sineusis," Bioxic Biotechnel, Biochem, 66(2):407-11 (2002).
DW 1995-348306, Sep. 12, 1995, JPX.
DW-1997-333338, Aug. 10, 1995, JPX.
Koh J. et al., "Natifatigue and ansistens offect of hot-water fraction from mycefa of Condyceps sineusis," Biol. Pharm Bull. 26(3):691-from mycefa of Condyceps sineusis. Biol. Pharm Bull. 26(3):691-

94 (2063).
Kuo C. et al., "Condyceps sinemis mycelium protects mice from group A streptococcal infection," Journal of Medical Microbiology

Primary Examiner - Chris R Tate Assistant Examiner — Randall Winston ABSTRACT

21 Claims, 2 Drawing Sheet



#### The Director of the United States Patent and Trademark Office

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The require ments of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

#### United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extensions.

Nicholas P. Ebdici

Qui m. Puson

Pharmaceutical composition for preventing and treating liver fibrosis or nonalcoholic fatty liver disease

•	Taiwan	TWI501771
		TWI554277

USA US8,858,954 US8,658,181

JP6050099 Japan

**European Union EP2644201B1** 

Methods for making and compositions comprising fermentation products of Cordyceps sinensis

USA

US8722056 B2

### The only Cordyceps sinensis owns approval from US FDA



US FDA confirmed that LivPhcD was a natural botanical product with decent quality safe enough to be used as dietary supplements' new ingredient in American market and therefore granted it a pre-market notification.

FDA agrees LivPhcD can:

- promote general health
- boost energy
- modulate physical functions



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

DATE: March 31, 2002

Dear Sir/Madame:

HOMEGI BIOTECH INTERNATIONAL CORP., Taipei, Taiwan would like to notify FDA of its intent to market a dietary supplement, "Sustotrong" which contains new dietary ingredients, in the US market. It has authorized Dr. Vann Lin of Marco Polo Technologies Inc. (Attachment 1) to be its representative who will handle matters regarding this notification. Sustotrong is a product of TCM Bio-Technology International. It is manufactured under contract by Sheng Chang Pharmaceutical Co. Ltd. and distributed by HOMEGI BIOTECH INTERNATIONAL CORP.

A. Name and complete address of Distributor

HOMEGI BIOTECH INTERNATIONAL CORP. 6th, Fil-2, No. 560, Section 4, Chung-Hsiao E, Road Shinyi Chiu, Taipei, Taiwan, 110
Renublic of China

Authorized representative in the US Dr. Yuan Lin Marco Poto Technologies, Inc. 5900 Conway Road Bethesda, MD 20817 301-897-5211 (phone); 301-530-5526 (fax) e-mail: ylindo@yahoo.com

B. Name of product and dietary ingredients

Name of product: Sustotrong
Sustotrong is in capsule form. Each capsule contains 500 mg. #- 10%.
Each package contains 90 capsules. There is no structure/function claim on the label
(Attachment 2—Package label).

5900 Conway Road, Bethesda, Maryland 20817 Phone: (301) 897-5211; Fax: (301) 530-5526



Public Health Service

Food and Drug Administration

IND 65,222

(4-11-02)

TCM-Biotechnology International Attention: Yuan Lin, Ph.D U.S. Representative 5900 Conway Road Bethesda, MD 20817

Dear Dr. Lit

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for TCM-700C.

We have completed our 30-day safety review of your application and as discussed with you in a telephone conversation with Jeff D. O'Neill of this Division on September 29, 2004 have concluded that you may proceed with your proposed clinical investigation.

If you have any questions, call Jeff O'Neill, Regulatory Health Project Manager, at 301-827-2335.

Sincerely

(See appended electronic signature page)

Debra Birnkrant, M.D. Director Division of Antiviral Drug Products Office of Drug Evaluation IV Center for Drug Evaluation and Research



### 泰宗生物科技股份有限公司

Address 24-8, No.97, Sec.1, Xintai 5<sup>th</sup> Rd., Xizhi Dist., Taipei City 22175, Taiwan

Tel +886-2-2697-2628

Fax +886-2-2697-2627

URL <a href="http://www.tcmbio.com/">http://www.tcmbio.com/</a>

**Email** <u>info@tcmbio.com</u>

**\ Thanks for Your Attention /**