DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: JAN 23 2003

0408 '03 JAN 27 P2:00

From: Consumer Safety Officer, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-821

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification:	Healthy Respiration
Firm:	American Research Institute of World Traditional Medicine
Date Received by FDA:	April 4, 2002
90-Day Date:	July 3, 2002

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Rhonda R. Kane

Rhonda R. Kane, M.S., R.D.

Attachments

95S-0316

RPT 126

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD

June 20, 2002

Runan Zhang, Esq.
Law Offices of Runan Zhang
2301 41st St, N.W., Suite 303
Washington, DC 20007

Dear Ms. Zhang:

This letter is in response to the notification, dated April 1, 2002, you submitted to the Food and Drug Administration (FDA) for a new dietary ingredient pursuant to 21 U.S.C. 350b(a)(2). FDA received your submission on April 4, 2002. Your letter informed us that you are representing the distributor American Research Institute of World Traditional Medicine that intends to market a product called "Healthy Respiration – Honey Suckle Farsythio & Root of Skullcap" that you assert is a new dietary ingredient. For the purposes of this response, FDA will use the name "Healthy Respiration" to refer to this substance.

Your notification states that your client intends to market Healthy Respiration as a dietary supplement containing dried powder or "pills of abstract" of the three botanicals. It is assumed by FDA that "abstract" is a misnomer for "extract" and that "pills" may be a misnomer for "pellets" noted in the description of the extract process for preparing Healthy Respiration.

The first column below lists the Latin binomial names of the three botanicals used to derive the combination of extracts in Healthy Respiration as stated in your notification. The second column below lists them again where we have corrected the spelling of both the genus name *Forsythia* and the authors' citations for two of the three ingredients and have stated all three ingredients in a format that conforms to the internationally accepted rules of botanical nomenclature. The third column below lists the plant parts used to prepare the extracts.

As Stated in the Notification	Corrected to Conform to Internationally Accepted Rules in Botanical Nomenclature	Plant Part Used
Lonicera Japonica Thumb	*Lonicera japonica* Thunb.	not specified
Farsythia Suspensa (thumb) Vah	*Forsythia suspensa* (Thunb.) Vahl	not specified
Scutellaria Baicalensis Georgi	*Scutellaria baicalensis* Georgi	root

Your notification states that the product will be packed into bags containing 5 gm of a mixture of 1.5 gm "Honey-suckle," 3 gm "Farsythio" and 1.5 gm "root of skullcap." Please note that this combination of ingredients adds up to 6 gm and not 5 gm. Your product instructions advise adults to take 1-2 bags 3 times daily by chewing or dissolved in hot water as a tea, and for children under the age of 2 years to take no more than half (1/2) a bag per day.

The law at 21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor of a dietary supplement that contains a new dietary ingredient 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.

FDA has carefully reviewed the information in your notification. From the information submitted, we cannot conclude that Healthy Respiration, when used as described in your notification or as suggested on your product's labeling, is reasonably expected to be safe.

The following observations form the basis of our conclusion:

1. Your brief reference to history of use of the "source" botanicals in China is not relevant to the proposed use of the "extracts" in Healthy Respiration.
2. The animal toxicity studies you submitted were very small in sample size, had no controls, did not provide histologic data, and did not clarify if the test substance was the same as Healthy Respiration.
3. No documentation was provided from the peer-reviewed scientific literature or other authoritative references that support your conclusion that chronic, long-term use of Health Respiration is safe.

Therefore, Healthy Respiration may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains new dietary ingredients for which there is inadequate information to provide reasonable assurance that such ingredients do 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).

Of additional concern to us are the particular statements made in your notification about the potential effect of Healthy Respiration. You state on page 2 of your letter that the

product may "prevent the infection from the respiratory system caused by virus" which implies that Healthy Respiration may be used to prevent a disease. The law at 21 U.S.C. 321(g)(1)(B) defines a drug as an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of a disease. Please be advised that if you intend to make any statements on the label or in the labeling of Healthy Respiration that claim it may prevent a respiratory disease from a virus or other cause, your product would be represented as a drug under 21 U.S.C. 321(g)(1)(B) and would be subject to regulation as a drug under the provisions of the Federal Food, Drug and Cosmetic Act. If you wish Healthy Respiration to be evaluated for its use in the treatment or prevention of any disease, you should contact FDA's Center for Drug Evaluation and Research, Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Your notification will be kept confidential for 90 days from the date of its receipt. After July 3, 2000, your notification and this response 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 in the notification will not be disclosed to the public.

Prior to July 3, 2002, you may wish to identify in writing specifically what information you believe is proprietary in your current notification for FDA's consideration. 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.

Should you have any questions concerning this matter, please contact me at (301) 436-2371.

Sincerely yours,

Virginia Z. Williams

for Felicia B. Satchell
Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements

LAW OFFICES OF RUNAN ZHANG

April 1, 2002

Division of Standard & Labeling Regulations
Office of Nutritional Products, Labeling & Dietary Supplements
Center for Food Safety & Applied Nutrition
Food & Drug Administration
5100 Paint Branch Parkway
Room 4D043
College Park, MD 20740-3835

RE: Premarket Notification for "Healthy Respiration -- Honey Suckle, Farsythio & Root of Skullcap"

Dear Sir or Madam:

This letter is to notify you that American Research Institute of World Traditional Medicine will function as the distributor for a Chinese herbal dietary supplement product "Healthy Respiration -- Honey-suckle, Farsythio & Root of Skullcap" in the United States.

The name and address of the distributor is American Research Institute of World Traditional Medicine at 5001 Russett Road, Rockville, MD 20853-2966.

The name of the new dietary ingredient is "Healthy Respiration -- Honey-suckle, Farsythio & Root of Skullcap." The new dietary product is a product of dried powder or pills of abstract of Chinese herbs -- honey-suckle, farsythio & root of skullcap. The Latin binomial names for each elements are Lonicera Japonica Thumb for Honey-Suckle, Farsythia Suspensa (thumb) Vah for Farsythio, and Scutellaria Baicalensis Georgi for Root of skullcap. The author for these herbs is Shizhen Li, who wrote "Bencao Gangmu" (means guideline of herbs) in Ming dynasty about 800 years ago listing the function of these herbs. These herbs are also listed in the "Chinese Herbs" edited by National Chinese Medicine Administration, published by Shanghai Science and Technology Publisher.

The product may strengthen the immune system and prevent the infection from the respiratory system caused by virus. No side effect has been reported so far. The health claim on the label will be "may strengthen immunity for healthy respiratory system".

The product will be packed into small bags with a mixture of 5g of three ingredients. The content of the ingredients in each bag is the mixture of 1.5g Honey-suckle, 3g Farsythio and 1.5g root of skullcap. The condition of use recommended in the label will be chewing or making a tea with hot water. Adult takes 1-2 bags a time and three times a day. Children under 2 should not take more than half bag a day.

Ministry of Health of China approved the product on April 28, 1993 as a non-prescription herbal medicine. The product has been sold on the Chinese market in the past

2301 41ST STREET, NW, SUITE 303 • WASHINGTON • DC 20007
PHONE: (202) 965-4348 • FAX: (202) 965-5842
EMAIL: RUNANZH@AOL.COM

RECEIVED 4/4/02

eight years. Toxicity test on the product conducted by the manufacturer showed that the product is toxicity free, safe for use and effective for strengthening the immune system and preventive for infection on respiration system caused by virus. There has been no report on any safety problems caused by using the product in the past eight years. All approved medicines have to be listed in the Chinese Medicine Dictionary. This dietary supplement is in the Chinese medicine dictionary as a proven safe Chinese herbal medicine with the method of making.

The person designated by the manufacturer is Mr. Changshan Liu, Director of American Research Institute of World Traditional Medicine, Inc. a nonprofit organization incorporated in Maryland.

Enclosed with this letter are translated materials on the information of the dietary supplement and the approval of the Ministry of Health of China for the production of the product and related information. Should you have any question concerning the product, please contact me at (202) 965-4348.

Sincerely,

Runan Zhang
Council for Petitioner

Acknowledgment signature of the designated person: Changshan Liu

Changshan Liu

Enclosure

CERTIFICATE OF NEW HERBAL MEDICINE AND APPROVAL FOR MANUFACTURE

93Z-22

Name of the product: Shuanghuanglian Chongji (Chinese)
Power of abstract of Honey Suckle, Farsythio & Root of Skullcap (English)

Type: the fourth category of Chinese herbal medicine (non-prescription)

Shape: power

Size: 5g bag

Manufacture organization: Harbin No. 1 Chinese Herbal Pharmaceutical Manufacturer

Applicant: same as above

Application No: (92) HYZ 09

Application date: Nov. 21, 1992

Result of application: approved

Certificate No. of New Medicine: (93) WYZ-21

Approval No.: (93) WYZ-14

Protection period: three years from April 28, 1993 to April 27, 1996

Attachment: product quality standard and instruction for usage

Notified office: Health Administration of Hailongjian Province

CC: Medicine Dictionary Committee of Ministry of Health, China Pharmaceutical Biomedicine Examination Office, Health Administrations and Medicine Examination Office of each province, Metropolitan city and area, Harbin No. 1 Chinese Herbal Pharmaceutical Manufacturer.

中华人民共和国卫生部

新药证书及生产批件

(93)Z-22号

新药名称	正式品名：双黄连冲剂 拉丁名： 汉语拼音：Shuanghuanglian Chongji				
类别	中药第四类	剂型	冲剂	规格	5g/袋
研究单位	哈尔滨中药一厂				
申请生产单位	哈尔滨中药一厂				
申请编号	(92)黑药申产字第09号	申请日期	1992年11月21日		
审批结论	同意生产。				
新药证书编号	(93)卫药证字Z-21号				
批准文号	(93)卫药准字Z-14号				
保护期	3年，自1993年4月28日至1996年4月27日				
附件	双黄连冲剂质量标准及使用说明书				
主送单位	黑龙江省卫生厅				
抄送单位	卫生部药典会，中国药品生物制品检定所，各省、自治区、直辖市卫生厅(局)及药品检验所，哈尔滨中药一厂				

中华人民共和国卫生部

1993年4月28日

TRANSLATION OF CHINESE MEDICINE DICTIONAY

~~POWER~~ Pellets OF ABSTRACT OF HONEY-SUCKLE, FARSYTHIO & ROOT OF SKULLCAP

Ingredients: honey-suckle – 1500g, farsythio – 3000g, root of skullcap –1500g

Method of making:

Shape: brown color pellets, tasted a little bitter and sweet.

Function and indication: cool and reduce sweet, antipyretic and detoxicate, release fever, cough and sore throat from cold.

Method of use and dosage: chew pellets or pure into hot water, 5g a time, three times a day, under 6 months, 1.0-1.5g a time, 6-12 months, 1.5-2.0g a time, 1 year to 3 years old, 2.0-2.5g a time or follow doctor's prescription.

Specification: 5g a bag

Storage: seal, keep it in the cool and dry place.

TRANSLATION OF CHINESE MEDICINE DICTIONAY

~~POWER~~ pellets OF ABSTRACT OF HONEY-SUCKLE, FARSYTHIO & ROOT OF SKULLCAP

Ingredients: honey-suckle – 1500g, farsythio – 3000g, root of skullcap –1500g

Method of making: slice root of skullcap, boil them with water three times. First time, two hours, second and third time, one hour each. Put the juice from three boilings together, filter the juice, reduce the juice to the density of 1.05-1.10 (at 80C), add 2mol/L hydrochloric acid liquid to adjust ph value to 1.0-2.0 at 80C, keep it warm for a hour, leave the juice still for 24 hours, filter, then, wash with water to adjust ph value to 5.0, then wash with 70% alcohol to adjust ph vale to 7.0. Leave the juice in low temperature to dry for later use. Merge honey-suckle and farsythio into warm water for half hour, cook them twice, one and half hour each time, filer the juice at each cool, then add the juice from two boils together, reduce the juice to paste at the density 1.20-1.25 (at 70-80C), cool it to 40C, add alcohol to make the content of alcohol to 75%, stir well, keep it still for 12 hours, separate and take the clear up layer liquid, add more alcohol to the remainder, stir, keep it still for 12 hours, filter, put alcohol liquid together, separate alcohol from the juice, reduced the juice to the paste of density of 1.30-1.32 (at 60-65C), dry it in low pressure. Add the paste of root of skullcap with the paste of honey-suckle and farsythio, dry, crush them power, add other supplements, stir, then make them into pellets, dry, get 1000g pellets.

Shape: brown color pellets, tasted a little bitter and sweet.

Function and indication: cool and reduce sweet, antipyretic and detoxicate, release fever, cough and sore throat from cold.

Method of use and dosage: chew pellets or pure into hot water, 5g a time, three times a day, under 6 months, 1.0-1.5g a time, 6-12 months, 1.5-2.0g a time, 1 year to 3 years old, 2.0-2.5g a time or follow doctor's prescription.

Specification: 5g a bag

Storage: seal, keep it in the cool and dry place.

双黄连颗粒

Shuanghuanglian Keli

【处方】 金银花 1500g　　黄芩 1500g　　连翘 3000g

【制法】 以上三味，黄芩切片，用水煎煮三次，第一次 2 小时，第二、三次各 1 小时，合并煎液，滤过，滤液浓缩至相对密度 1.05～1.10（80℃测），于 80℃时加 2mol/L 盐酸溶液调节 pH 值至 1.8～2.0，保温 1 小时，静置 24 小时，滤过，沉淀用水洗至 pH 值 5.0，继用 70%乙醇洗至 pH 值为 7.0，低温干燥，备用；金银花、连翘加水温浸半小时后，煎煮 2 次，每次 1.5 小时，分次滤过，合并滤液，浓缩至相对密度为 1.20～1.25（70～80℃测）的清膏，冷至 40℃时，搅拌下缓缓加入乙醇，使含醇量达 75%，充分搅拌，静置 12 小时，滤取上清液，残渣加 75%乙醇适量，搅匀，静置 12 小时，滤过，合并乙醇液，回收乙醇至无醇味，并浓缩成相对密度为 1.30～1.32（60～65℃）的清膏，减压干燥，与黄芩提取物粉碎成细粉，加入糊精等辅料适量，混匀，制成颗粒，干燥，制成 1000g，即得。

【性状】 本品为棕黄色的颗粒；气微，味苦，微甜。

【鉴别】 （1）取本品 1g，加 75%乙醇 10ml，置水浴中加热振摇使溶解，滤过，滤液作为供试品溶液。另取黄芩苷、绿原酸对照品，分别加 75%乙醇制成每 1ml 含 0.1mg 的溶液，作为对照品溶液。照薄层色谱法（附录Ⅵ B）试验，吸取上述三种溶液各 1～2μl，分别点于同一聚酰胺薄膜（5cm×7cm）上，以醋酸为展开剂，展开，取出，晾干，置紫外光灯（365nm）下检视。供试品色谱中，在与对照品色谱相应的位置上，显相同颜色的荧光斑点。

（2）取本品 0.5g，加甲醇 10ml，置水浴中加热使溶解，滤过，滤液作为供试品溶液。另取连翘对照药材 0.5g，加甲醇 10ml，置水浴上加热回流 20 分钟，滤过，滤液作为对照药材溶液。照薄层色谱法（附录Ⅵ B）试验，吸取上述两种溶液各 5μl，分别点于同一以羧甲基纤维素钠为黏合剂的硅胶 G 薄层板上，以氯仿-甲醇（5∶1）为展开剂，展开，取出，晾干，喷以 10%硫酸乙醇溶液，在 105℃加热数分钟。供试品色谱中，在与对照药材色谱相应的位置上，显相同颜色的斑点。

【检查】 应符合颗粒剂项下有关的各项规定（附录Ⅰ C）。

【含量测定】 照高效液相色谱法（附录Ⅵ D）测定。

色谱条件与系统适用性试验　用十八烷基硅烷键合硅胶为填充剂；甲醇-水-冰醋酸（50∶50∶1）为流动相；检测波长为 274nm。理论板数按黄芩苷峰计算应不低于 1500。

对照品溶液的制备　精密称取黄芩苷对照品 10mg，置 100ml 量瓶中，加 50%甲醇适量，置水浴中振荡，使溶解，放置至室温，并稀释至刻度，摇匀，即得（每 1ml 中含黄芩苷 0.1mg）。

供试品溶液的制备　取装量差异项下的本品约 0.5g，研细，精密称定，置 50ml 量瓶中，加 50%甲醇适量，超声处理 20 分钟使溶解，放置至室温，加 50%甲醇稀释至刻度，摇匀，滤过，精密量取续滤液 5ml，置 10ml 量瓶中，加 50%甲醇稀释至刻度，摇匀，即得。

测定法　分别精密吸取对照品溶液和供试品溶液各 5μl，注入液相色谱仪，测定，即得。

本品每袋含黄芩以黄芩苷（$C_{21}H_{18}O_{11}$）计，不得少于 150mg。

【功能与主治】 辛凉解表，清热解毒。用于外感风热引起的发热、咳嗽、咽痛。

【用法与用量】 口服或开水冲服，一次 5g，一日 3 次；6 个月以下，一次 1.0～1.5g；6 个月至一岁，一次 1.5～2.0g；一岁至三岁，一次 2.0～2.5g，三岁以上儿童酌量或遵医嘱。

【规格】 每袋装 5g

【贮藏】 密封，置阴凉干燥处。

CONFIRMATION

Experimental Project: The experiment for acute, toxicity and long term toxicity of double copts chinemisis oral liquid

Project Dirctor: Peng Kerang

Research Institute: The Pharmacodynamics Laboratory, the Second Chinese Tradiational Medicine Factory, Harbin Drug Company Limied

Experiment Time: October, 1995 – Noverber, 1995

The above experiment was conducted by The Pharmacdynamics Laboratory, the Second Traditional Chinese Medicine Factory, Harbin Drug Company Limited.

It is hereby to confirm

The Research Institute, the Second Tradiational Chinese Medicine Factory, Harbin Drug Company Limited

Director: Peng Kerang

May, 1999

Date of Experiment on Acute Toxicity of Double Copts Chinemisis Oral Liquid Toxicity,

The Research Institute, Second Traditional Chinese Medicine Factory of Harbin

Experimental materials

1. **Medicine:** Double Copts Chineminisis Oral Liquid, produced by Harbin Huili Drug Company limited. Lot No. 950912.
Function and indications: Cool and reduce sweet, antipyretic and detoxicate. Relief fever, coughs and sore throat.
Directions: Take this medicine 20ml each time orally, three times a day. Children need to reduce dose or call doctor.
Standards: Each 10ml equal to 15g raw medicine.
Animals: Give this medicine to, five males and five females of mice, weight 19-21g.

2. **Animals:** Kunming rats, provided by Animal house of Heilongjiang Tumor Research Institute.
Methods and result:
1) Pre-experiment
Taking ten mice, weight 19-21g, half males and half females, Pour medicine down to their stomach. 0.8ml/mice.
The result of obsvertion: The mice were still alive in seven days and did not have any abnormal phenomena, not measure LD50 could be detected.

2) Measurement of the greatest endurance
Give this medicine to weight 18-22g, five males and five females mice, Pouring medicine down to their stomach. 1ml for each and give them 3 times in 24 hours. (At the greatest concentration and the greatest volume)
The result of obsvertion: The mice didn't have any abnormal phenomena when giving the medicine at first time. But at the second time, the animals became quiet and were not as active as before. At the third time, the animals still were not active, no other abnormal phenomena. Next day they resumed their normal activities. The scientists didn't find any died animals in seven days. This time the dose was 150ml/kg, equals to raw medicine225g/kg, was the 125 times in clinical.

A brief sum-up:

It is safe to take Double Copts Chineminisis Oral Liquid orally. greatest endurance of mice is not lower than raw medicine 225g/kg, equals to 125 times in clinical for human.

Data of Experiment on Acute Toxicity of Double Copts Chinemisis Oral Liquid Toxicity,

The Research Institute, Second Traditional Chinese Medicine Factory of Harbin

October 8, 1995

Experimental materials

1. **Medicine:** oral liquid of Honey Suckle, Farsythio & Root of Skullcap, produced by Harbin Huili Drug Company limited. Lot No. 950912.
   Function and indications: Cool and reduce sweet, antipyretic and detoxicate. Relief fever, coughs and sore throat.
   Directions: Take this medicine 20ml each time orally, three times a day. Children need to reduce dose or call doctor.
   Standards: Each 10ml equal to 15g raw herbal medicine.
   Test subject: Give this medicine to, five males and five females of mice, weight 19-21g.

2. **Animals:** Kunming rats, provided by Animal house of Heilongjiang Tumor Research Institute.
   Methods and result:
   1) Pre-experiment
      Taking ten mice, weight 19-21g, half males and half females, Pour medicine down to their stomach. 0.8ml/mice.
      The result of obsvertion: The mice were still alive in seven days and did not have any abnormal phenomena, LD50 could be detected.

   2) Measurement of the greatest endurance
      Give this medicine to weight 18-22g, ten males and ten females mice, Pouring medicine down to their stomach. 1ml for each and give them 3 times in 24 hours. (At the greatest concentration and the greatest volume)

The result of obsvertion: The mice didn't have any abnormal phenomena when giving the medicine at first time. But at the second time, the animals became quiet and were not as active as before. At the third time, the animals still were not active, no other abnormal phenomena. Next day they resumed their normal activities. The scientists didn't find any died animals in seven days. This time the dose was 150ml/kg, equals to raw herbal medicine 225g/kg, equal to 125 times of dosage for clinical use for adults.

Conclusion:

It is safe to take oral liquid of honey suckle, farsythio and root of skullcap by human. The greatest endurance of mice is not less than raw medicine 225g/kg, equals to 125 times in clinical dosage for human.

Appendix:

1. The brief introduction of the Research Institute, the Second ChineseTraditiona Medicine Factory, Harbin Drug Company Limited; (including major equipment and facilities)

2. Information about the scientists in the Research Institute

3. The biograthy of the research project director

The Brief Introduction of Research Institute, Second Traditional Chinese Medicine Factory, Harbin Drug Company Limited

The institute belongs to the Second Traditional Medicine factory, Harbin Drug Company Limited. Currently there are 48 scientists in the institute, including senior scientists, 8 scientists, and 39 junior scientists. Among them, one has Master degree and 17 are Master degree graduated students.

The institute is consisted of traditional Chinese medicine and new medicine development laboratory, traditional Chinese medicine and pharmacodynamics laboratory, traditional Chinese medicine preparation laboratory, central instrument room, synthesizes medicine laboratory. In addition, there are library and pharmacodynamics animal room, etc.

At present, the institute has hundreds of research equipment. Including: HPLC, ultraviolet spectrometer, atomic absorption chromatographic detector, small scale spray desiccator, small scale freeze desiccator, eight-lead physiological exam instrument, automatic tissue microtome, electrocardiograph, platelet assemble instrument, ultrasonic, super-filter instrument, etc.

Appendix:

Experimental facilities

The Research Institute of Second Traditional Chinese Medicine Factory, Harbin Drug Company Limited

Director: Peng Kerang

Experimental Facilities and Equipment

The Research Institute, the Second Traditional Chinese Medicine Factory, Harbin Drug Limited

Name	Manufacturer	Catologue No.	the date of Purchase	raise	Place for setting	Executive Professor	Purpose of Purchase
Electric Respirator	Shanghai, China	SC-5	1997	independent	Pharmacodynamics Lab.	Zhu Jinwu	research
Mult-function Computer High Frequency Electric Knife	Beijing, China	DG-300 BN	1997	independent	Pharmacodynamics Lab.	Zhu Jinwu	research
Three-Lead Electronic Picture Machine	Shanghai, China	ECG-8110P	1997	independent	Pharmacodynamics Lab.	Zhu Jinwu	research
Multi-line Physionlogical Recorder	Chengdu, China	RM-6280C	1997	independent	Pharmacodynamics Lab.	Zhu Jinwu	research
Platelet Gather Plasma Tester	Beijing China	PAPER-1	1998	independent	Pharmacodynamics Lab.	Zhu Jinwu	research

Experimental Facilities and Equipment

The Research Institute, the Second Traditional Chinese Medicine Factory, Harbin Drug Limited

Name	Manufacturer	Catologue No.	the date of Purchase	raise	Place for setting	Executive Professor	Purpose of Purchase
High Pressure HPLC	America	SD-200	1994	independent	Central Equipment Room	Sun Lixin	research
High Pressure HPLC	America	WOTERS-515	1998	independent	Central Equipment Room	Sun Lixin	research
Ultraviolet Spectrometer	Japan	FTIR-8700	1998	independent	Central Equipment Room	Sun Lixin	research
Freezing Desiccator	Germany	GT-2	1995	independent	Central Equipment Room	Sun Lixin	research
Spray Desiccator	Japan	DL-40	1994	independent	Central Equipment Room	Sun Lixin	research
Thin Section Chromatogram Scanner	Beijing, China	CS9300	1996	independent	Central Equipment Room	Sun Lixin	research

Experimental Facilities and Equipment

The Research Institute, the Second Traditional Chinese Medicine Factory, Harbin Drug Limited

Name	Manufacturer	Catologue No.	the date of Purchase	raise	Place for setting	Executive Professor	Purpose of Purchase
hydroextractor	Germany	NMS-70	1998	independent	Pharmacodynamics Lab.	Zhu Jingwu	research
Auto Color Machine	Germany	HMP-110	1998	independent	Pharmacodynamic Lab.	Zhu Jingwu	research
Microtome	Germany	HMZ40E	1998	independent	Pharmacodynamic Lab	Zhu Jingwu	research
Baomai Work Station	Germany	SP280	1998	independent	Pharmacodynamic Lab.	Zhu Jingwu	research
Biological Microscope	Germany	AXIO106 KE	1998	independent	Pharmacodynamic Lab.	Zhu Jingwu	research
Atomic Absorption Chromatographic	America	AAS3300	1995	independent	Central Equipment Room	Sun Lixin	research

Experimental Facilities and Equipment

The Research Institute, the Second Traditional Chinese Medicine Factory, Harbin Drug Limited

Name	Manufacturer	Catologue No.	the date of Purchase	raise	Place for setting	Executive Professor	Purpose of Purchase
Blood Viscosimeter	Beijing, China	LG-R-80	1998	independent	Pharmacodynamics Lab.	Zhu Jinwu	research
Vigour Analyser	Switzer -land	COMPA -RT-2	1998	independent	Pharmacodynamics Lab.	Zhu Jinwu	research

Information About Scientists in the Research institute

Director:

Name: Peng Kerang The title of a professional post: research fellow, senior engineer

Final degree: B.S. Research field: the form of the Traditional Chinese Medicine
The new medicine of Traditional Chinese Medicine

Name: Wang Xinying The title of a professional post: senior engineer

Final degree: B.S. Research field: the Form of the Traditional Chinese Medicine,
New medicine

Research Scientists:

Name	The title of professional post	Research fiel
Jia Jiming,	associate research fellow,B.S.,	Traditional Chinese Medicine Chemistry
Zhu Jinwu,	associate research fellow,M.S.,	Traditional Chinese Medicine pharmacology
Ma Zhiqiang,	assistant research fellow,B. S.,	Traditional Chinese Medicine chemistry
Zhu Fengqin,	associate research fellow, B. S.,	Traditional Chinese Medicine pharmacology
Lu Chunling,	assistant research fellow, B. S.,	biochemistry pharmacology
Xie Liwen,	assistant research fellow, B. S.,	biochemistry pharmacology
Cui Zhijie,	associate research fellow, B. S.,	medicine analyse
Guan Xi,	associate research fellow, B. S.,	medicine preparation
Yang Jing,	associate research fellow, B. S.,	Traditional Chinese Medicine preparation

Name	The title of professional post	Research field
Huang Xuchun,	associate research fellow, B. S.,	Traditional Chinese Medicine preparation
Wu Quanzhen,	associate research fellow, B. S,	medicine analyse
Wang Lixin,	associate research fellow, B. S.,	Traditional Chinese Medicine preparation
Li Dianming,	associate research fellow, B. S.,	medicine analyse

(Toxicity) The Research Project Director's Working Experience

Personal Information

Last Name: Peng
First Name: Kerang
Address: 17 Sgangyiu Street Daoli Distrit, Harbin, and P. R. CHINA
Identification: No. 230103540105161
Home phone: 4640857 Work phone: 2543681

Education

1972-1980	Heilongjiang Business School, Major in Traditional Chinese Medicine

Working Experience

1981-1983	Assistant engineer, Second Factory of Harbin Traditional Chinese Medicine
1983-1991	Engineer, Second Factory of Harbin Traditional Chinese Medicine
1991-1997	Senior engineer, Second Factory of Harbin Traditional Chinese Medicine
1997-present	Research fellow, senior engineer, Second Factory of Harbin Traditional Chinese Medicine

Publication

Publications Abroad

Fab. 1996	Title: Improved Method for the Determination of Calcium, Chloride Content in Peritoneal Dialysate Journal: Analytical Abstracts Volume 58 (2)

Publications in China

May, 1995	Title: Improvement for Measuring in Chlorine Tungsten Content in Fu Me Tu Gang Liquid. Journal of Medicine Analyse No. 5, 1995
April, 1994	Title: Design for Powder Needle Tunnel and Asepsis Room New Type Air-condition System Journal of Heilongjiang Medicine No. 4, 1994
Feb. 1994	Title: Determine the Content of cephalosporin by the Method of Optical Rotation Journal of Heilongjiang Medicine No. 2, 1994
May, 1993	Title:An Approach in Accuracy of the Alcoholate Concentration in Making Traditional Chinese Medicine Journal of Heilongjiang Medicine No. 5, 1993
Nov. 1985	Title: the Relationship between Density and Temperature of Ci 5 plus water boiled medicinal extract Journal of Phamaceutics Journal No. 11, 1985
Nov. 1983	Title: Eleminination of Precipitation of Ginseny Extract in Five Plus by Ajustment of PH Journal of Traditional Chinese Medicine Research No, 11, 1983
Dec. 1983	Title: An Approach in Density of Traditional Chinese Medicine water boiled Medicinal Extract Journal of Phamaceutics Journal No. 12, 1983