

LAW OFFICES OF RUNAN ZHANG

November 12, 2002

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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 -- Honeysuckle,
Forsythio & 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 -- Honeysuckle, Forsythio & Root of Skullcap" ("Healthy Respiration") 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, Forsythio & Root of Skullcap." This product has been on the Chinese market since 1993 in the forms of refined powder for injection, oral liquid and spray, mixture/powder in small bags for tea. The ration of the mixture of each ingredient and the production procedure is the same for all different forms of the product. The only difference in the production is the final formation procedure, which will form the final products in different shapes. The new dietary product to be marketed in the United States will be in the forms of dried powder/mixture of extract of Chinese herbs -- honeysuckle, forsythio & root of skullcap. Oral liquid and spray, medicated candies are also considered for the market needs.

The Latin binomial names for each elements are:

Lonicera Japonica Thunb for Honey-Suckle, flowers used;

Forsythia Suspensa (thunb) Vahl for Forsythio, seeds used;

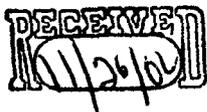
Scutellaria Baicalensis Georgj for Root of skullcap, stem and roots used.

The recorded history of these three herbs for medical function can be traced back to thousands years ago to the Chinese history. The author for these herbs is Shizhen Li, who wrote "Bencao Gangmu" (means guideline of herbs) in Ming dynasty about 800 years ago

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listing the function of these herbs. Xingyan Sun, who wrote "Shennong Bencao Jing" (meaning collection of herbs) collected these three herbs in Qing dynasty about 500 years ago. These herbs are also listed in the "Chinese Herbs" edited by National Chinese Medicine Administration, published by Shanghai Science and Technology Publisher in 2000. These three herbs are also collected into the English book, *Herbs*, by Lesley Bremness, published by Dorling Kindersley in London, New York and Stuttgart in the Western world in the recent years.

The product may strengthen the immune system of the respiratory system. No side effect has been reported so far. The health claim on the label will be "may strengthen immunity for healthy respiratory system". Since 1992, there were professional conferences and seminars discussing the medical function and safety of the new non-prescription drug – Shuanghuanglian Powder ("Healthy Respiration") in the Chinese medical field. A great number of articles on the application of the drug and result of the application were published in the medical journals in China. All the articles reported the positive result of the application of the herbal medicine.

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 Honeysuckle, 2g Forsythia 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 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. In the United States, there were 74 patents approved by the US Patent Office concerning the use of Honeysuckle, 43 patents approved by the US Patent Office concerning the use of Forsythia, and 41 patents approved by the US Patent Office for the use of skullcap during 1996 to 2002. From the list of the approved patents, it shows that many of the patents concerning these three herbs are dealing with medical functions and use. Although, I have not found any dietary supplement using these herbs, these herbs are not completely new or foreign to the US market and consumers.

The person in charge of the designated by the manufacturer is Mr. Changshan Liu, Director of American Research Institute of World Traditional Medicine, Inc. a nonprofit organization incorporated in Maryland. The manufacturer is Harbin Pharmaceutical Group Co., Ltd. Second Chinese Medicine Factory, which passed the GMP inspection and holds a valid certificate of GMP issued by China State Drug Administration.

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. They include the following:

1. Translated the certificate of new herbal medicine and approval for manufacture of Shuanghuanglian Chongji – Healthy Respiration,
2. Data of experiment on acute toxicity of Shuanghuanglian Chongji oral liquid toxicity,
3. Information about the research institute which conducted the experiment,
4. Translation of Chinese medicine dictionary on Healthy Respiration,
5. Introduction information on the Healthy Respiration powder prepared by the manufacturer on the related data and information concerning its use and medical function,
6. Article entitled Effects of Shuanghuanglian (Healthy Respiration) Treatment of Child Pneumonia published in Chinese Journal of Integrated Traditional and Western Medicine in 1994,
7. Article entitled Study on Antivirus Effect of Shuanghuanglian (Healthy Respiration) Injection published in Chinese Traditional and Herbal Drugs in 2002,
8. Article entitled Clinical Observation of Shuanghuanglian (healthy respiration) in treating late term malignant cancer with complication of lung infection published in the Practical Journal of Integrating Chinese with Modern Medicine in 1998,
9. Article entitled Clinical Observation on treatment of child pneumonia by Shuanghuanglian (healthy respiration) published in Shanghai Journal of Traditional Chinese Medicine in 1994,
10. Article entitled Clinical Observation of Treatment by Shuanghuanglian of 125 cases of child upper respiratory tract infection in Lishizhen Medicines and Materia Medica Research in 1999,
11. Article entitled Case study: clinical observations of treating 140 child infectious disease with Shuanghuanglian (healthy respiration) published in Chinese Journal of Hospital Pharmacy in 1998,
12. Article entitled 80 cases of ministering Shuanghuanglian (healthy respiration) injection in treatment of pediatric respiratory tract infection published in Shaanxi Journal of Chinese Traditional Medicine in 1993,
13. Certificate of Good Manufacturing Practices for Human Drugs People's Republic of China for the manufacturer of the proposed dietary supplement,

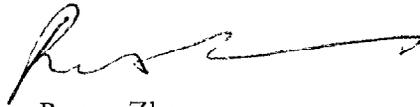
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14. List of US patents concerning the three herbs used for different functions, and

15. Copy of the English book on the three herbs, *and Chinese books.*

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

Enclosure

*P.S. Shuang Huang Lian is the Chinese name
for Healthy Respiration*