



Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

OCT 20 2004

Runan Zhang
Law Offices of Runan Zhang
2301 41st Street, NW
Suite 303
Washington, DC 20007

Dear Mr. Zhang:

This is to inform you that the notification you submitted, dated July 19, 2004, on behalf of your client, American Research Institute of World Traditional Medicine, pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on August 6, 2004. Your notification describes "Shuanghuanlian-Healthy Respiration", consisting of three new dietary ingredients (extract of Honeysuckle (*Lonicera japonica* Thunb), extract of Forsythia (*Forsythia suspensa* (Thunb) Vahl), and extract of Root of Skullcap (*Scutellaria baicalensis* Georgi)) which you intend to market as a dietary supplement product called "Shuanghuanlian-Healthy Respiration".

According to the notification, American Research Institute of World Traditional Medicine intends to sell the proposed new dietary supplement product, "Shuanghuanlian-Healthy Respiration", in powder/grain form which will be packaged in small bags containing a 5 g mixture of three botanical extracts: 1.5 g extract of Honeysuckle, 2 g extract of Forsythia and 1.5 g extract of Root of Skullcap. The notification states that "the condition of use recommended in the label will be chewing (the bags) or making drinks with hot or cold water." The notification further states that "adults take 1-2 bags at a time, three times a day. Children under 2 should not take more than one-half of a bag per day."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing 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 must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is 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 new 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 dietary supplement is considered 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 or injury.

FDA has carefully considered the information in your submission, and the agency has concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing “Shuanghuanlian-Healthy Respiration” will reasonably be expected to be safe.

Your notification states that there is a long history of use of the botanical components of the product, “Shuanghuanlian-Healthy Respiration”, however, there is no documentation of this claim in your notification.

Your notification fails to clearly identify the composition and manufacturing process for the new dietary ingredient “Shuanghuanlian-Healthy Respiration”. Your notification does not contain any information about the source of the raw botanical materials, levels of the active ingredients, product specification, methods of analysis, and purity of the proposed dietary supplement, “Shuanghuanlian-Healthy Respiration”. Information about your method of manufacture may have helped FDA to identify your product.

Moreover, all of the information and reports included in the notification appear to involve intravenous administration of a medicinal product whose relationship to the proposed new dietary ingredient or the dietary supplement which contains it is unclear. According to the notification, the test material was stated to be “Shuanghuanlian-Healthy Respiration” and was described as a “powder in an ampule for injection”. It is not evident that the test substances used in the referenced studies are qualitatively or quantitatively similar to your “Shuanghuanlian-Healthy Respiration”, or how these studies are relevant to evaluating the safe use of your new dietary ingredient under the recommended conditions of use.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that the “Shuanghuanlian-Healthy Respiration” product, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of August 6, 2004. After the 90-day date, the notification will be placed on public display at FDA's Division of Docket Management in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Linda Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,

A handwritten signature in cursive script that reads "Linda S. Pellicore".

for Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition