



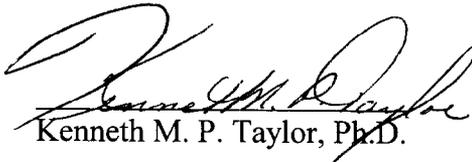
Memorandum

0652 '03 FEB 25 P1:55

Date: February 13, 2003
From: Chemist, 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 – Honeysuckle, Forsythio, and Root of Skullcap
Firm: American Research Institute of World Traditional Medicine.
Date Received by FDA: November 26, 2002
90-Day Date: February 24, 2003

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.


Kenneth M. P. Taylor, Ph.D.

Attachments

95S-0316

RPT157



FEB 07 2003

0653 '03 FEB 25 P1:55

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

Dear Ms. Zhang:

This letter acknowledges receipt of a new dietary ingredient notification, dated November 12, 2002, submitted to the Food and Drug Administration (FDA) for a new dietary ingredient pursuant to 21 U.S.C. 350b(a)(2) [section 413 (a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)] and 21 Code of Federal Regulations (C.F.R.) 190.6. FDA received your submission on November 26, 2002. Your submission notified FDA that American Research Institute of World Traditional Medicine intends to function as the distributor and market a product called "Healthy Respiration – Honey Suckle, Forsythio & Root of Skullcap" as a new dietary ingredient. This notification represents a resubmission of an earlier notification dated April 1, 2002, that was received by FDA on April 4, 2002. FDA responded to this notification on June 20, 2002, indicating that your notification did not comply with the requirements of 21 CFR 190.6 because it failed to provide a reasonable assurance of safety when used under the conditions recommended. You were further advised that because your prior notification did not satisfy regulatory requirements, American Research Institute of World Traditional Medicine could not legally market a dietary supplement containing "Healthy Respiration – Honey Suckle Forsythio & Root of Skullcap". For the purposes of this response, FDA will use the name "Healthy Respiration" to refer to this substance.

Your notification further states that the product will be marketed as an herbal dietary supplement under the trade name "Healthy Respiration". The product is to be packed into small 5g bags consisting of a mixture of 1.5g Honeysuckle (flowers), 2g Forsythio (seeds), and 1.5g root of skullcap (stems and roots). The product may be ingested by either chewing or by brewing a tea. The adult dose is 1-2 bags 3 times per day, and children under age 2 years should not consume greater than one-half 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 considered the information in your submission, and the agency has significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing Healthy Respiration will reasonably be expected to be safe. In the report titled “Date of Experiment on Acute Toxicity of Double Coptis Chinensis Oral Liquid Toxicity,” “Double Coptis Chinensis” have been crossed through and replaced by the handwritten notation “Healthy Respiration.” Section 2 of this report states that Kunming rats are the test subjects and then later indicates mice. This report is not useful for evaluating safety of the ingredient that is the subject of the notification. Additional information is provided with the notification on Shuanghuanlian Powder. Studies included administration of this substance to various animal test subjects including mice, rats, cats, dogs, and Guinea pigs. The notification also includes clinical reports in which Shuanghuanlian Powder was administered to hospital patients for treating childhood pneumonia and lung infections in lung cancer patients. However, it cannot be determined from the information provided that the formulation of Shuanghuanlian Powder is the same as in Healthy Respiration. Furthermore, all of the studies performed with Shuanghuanlian Powder appear to have involved intravenous, intravenous drip, or intraperitoneal administration of the powder. These reports included with the notification appear to involve a medicinal product whose relationship to the substance of the notification is not explained. Such information is likely of limited utility in evaluating the safety of a dietary supplement containing Healthy Respiration. Your notification fails to explain the relationship between your substance and the substance used in the studies. Therefore, your notification does not meet the requirements establishing history of use or other evidence of safety when used as recommended or suggested as required by 21 CFR 190.6(b)(4).

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that “Healthy Respiration – Honey Suckle, Forsythia & Root of Skullcap”, 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).

Page 3 – Ms. Runan Zhang, Esq.

Your notification will be kept confidential for 90 days from the date of its receipt. After February 24, 2003, 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 February 24, 2003, 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,

A handwritten signature in cursive script that reads "Felicia B. Satchell".

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