



Mr. Michael G. Jeffers
JML Marketing, Inc.
700 North Walnut Street
Bloomington, Indiana 47408

OCT 26 2006

Dear Mr. Jeffers:

This is to inform you that the notification, dated August 4, 2006, that you submitted 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 14, 2006. Your notification concerned the substance that you called "Angelica gigas Nakai (Korean) Extract" that you identify as a new dietary ingredient. According to your notification, "Angelica gigas Nakai (Korean) Extract" is derived from the roots of *Angelica gigas* Nakai.

Your notification refers to the conditions of use of "Angelica gigas Nakai (Korean) Extract" as a "bulk dietary ingredient" in dietary supplement products with "suggested 'ingredient' dosage rates to the recipient ... [of] 250 mgs twice 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 21 U.S.C. 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 "Angelica gigas Nakai (Korean) Extract" will reasonably be expected to be safe.

The composition of "Angelica gigas Nakai (Korean) Extract" is unclear to FDA. For example, the analytical information included in your notification was too limited to assess the validity of statements in the notification concerning the composition of the ingredient. In addition, your notification states that "Angelica gigas Nakai (Korean) Extract" is used to make a product you call Jointwell™ and a product you call Joinwell™. However, the amount of "Angelica gigas Nakai (Korean) Extract" in these products is variously described as 26.0% and "solid content greater than 10%" and the product(s) contains several other ingredients such as glucosamine. Thus it is unclear to FDA how "Angelica gigas Nakai (Korean) Extract" is qualitatively or quantitatively related to Jointwell™ or Joinwell™ or how the information you provided about those products is relevant to an evaluation of the safe use of "Angelica gigas Nakai (Korean) Extract".

In addition, your notification contains information about a clinical study of "GWB78" which you assert is identical to "Angelica gigas Nakai (Korean) Extract". It is unclear to FDA how the information in this study provides a basis for the safety of a product containing your ingredient. For example, the dose used in the study is described as "0.5mg of GWB78 powder divided by twice in the morning and evening...". This serving level is significantly lower than the 500 mg serving level that will be suggested or recommended in the labeling of dietary supplement products containing "Angelica gigas Nakai (Korean) Extract". Furthermore, the information in the study was inadequate to establish the safety of the tested material. For example, FDA was unable to evaluate the blood chemistry of the subjects in the study based on the provided table of laboratory values that contained no units of measurement.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Angelica gigas Nakai (Korean) Extract", 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 14, 2006. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch 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 Theresa Prigmore at (301) 436-1446.

Sincerely yours,

A handwritten signature in black ink that reads "Linda S. Pellicore". The signature is written in a cursive style with a large, prominent initial "L".

Linda S. Pellicore, Ph.D.

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