



Rakesh M. Amin  
SK Chemical Co., Ltd.  
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OCT 19 2006

Dear Mr. Amin:

This is to inform you that the notification, dated July 25, 2006, you submitted pursuant to 21 U.S.C. 3501b(a)(2) (section 413 of the Federal Food, Drug, and Cosmetic Act (the Act)) was received by the Food and Drug Administration (FDA) on August 7, 2006. Your notification concerns the new dietary ingredient "*Clematis mandshurica* Rupr.," that you intend to market as a dietary supplement product called "SKI306X." According to your notification, "SKI306X" contains extracts of *Clematis mandshurica*, *Trichosanthes kirilowii*, and *Prunella vulgaris*.

According to your notification, the new dietary ingredient will be in the form of tablets that will contain "200-300 mg of *Clematis* extract (400-600mg of active ingredient)." The recommended conditions of use of "*Clematis mandshurica* Rupr.," are "[a]s a dietary supplement ...take one tablet, 2-3 times daily."

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 significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing "*Clematis mandshurica* Rupr." will reasonably be expected to be safe. Based on the information in your submission, FDA was unable to determine the identity of your new dietary ingredient, "*Clematis mandshurica* Rupr." Your notification does not adequately

describe a history of use of *Clematis mandshurica* Rupr., or the combination of the three herbal extracts contained in "SKI306X." The extraction process is described in very general terms. Your notification has specifications for the active ingredient, oleanolic acid, and a second substance, rosmarinic acid. However, the relationship between these specifications and the specifications for "SKI306X" in the published article is not clear. Your notification does not address the source of the plant material, parts of the plants used, harvesting, or handling of material prior to extraction. Also, your statement regarding how much *Clematis mandshurica* Rupr. material is present in the final product appears to be incorrect.

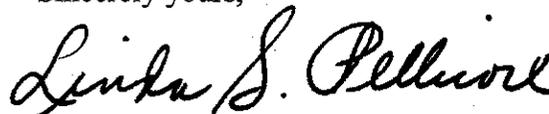
Your notification contains the results of human and animal studies. The animal studies appear to use the same botanical extract that is included in the dietary supplement product "SKI306X." The human studies appear to use the same botanical extract "with general additives". It is unclear whether the preparations used in the human trials are the same as the preparations that will be marketed, therefore, it is unclear to FDA how "SKI306X" is qualitatively or quantitatively similar to the material used in the clinical trials and thus, it is unclear how the information submitted is relevant the safe use of your dietary ingredient contained in your dietary supplement product.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "*Clematis mandshurica* Rupr.," 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 7, 2006. 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 Theresa Prigmore at (301) 436-1446.

Sincerely yours,



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