



NOV 22 2005

Ms. Dierdre Allan
pH Sciences, Inc.
17230 12th Avenue, NE
Seattle, Washington 98155

Dear Ms. Allan:

This is to inform you that the notification, dated September 6, 2005, that you submitted on behalf of pH Sciences, Inc., 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 September 9, 2005. Your notification concerns the substances that you call Alka-Plex® that you identify as a new dietary ingredient in a dietary supplement product that you call "pH Balance™".

According to your notification, "A single serving size of pH Balance™ is one tablet. The suggested use is two to four tablets per day, not to exceed six tablets per day. PH Balance™ is not recommended for long term use. The label suggests that the user consult with a physician prior to using the supplement. The label suggests that the user consult a physician prior to use if the user is presently taking any medications or is under a physician's care. Precautions are listed on the supplement label follow (sic): Contraindicated for women who are pregnant or nursing; Contraindicated for individuals with impaired kidney function, kidney disease."

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 Alka-Plex® will reasonably be expected to be safe.

FDA was unable to determine the identity of Alka-plex®. According to your notification (section 3.1) a 1000 mg tablet made from Alka-Plex® granules contains "Magnesium (as magnesium hydroxide) 4mg" and "Calcium (as Calxium [sic] carbonate- 220mg" which FDA calculates as 0.4% Mg and 22% Ca, respectively. However, an assay report in your notification, dated September 2, 2005, reported the magnesium concentration to be 0.180-0.194% in three different samples and the calcium concentration to be 25.1-25.6% in the same samples. Thus, according to your notification, the actual magnesium concentration in your product is significantly lower and the actual calcium concentration somewhat higher than the stated amounts in your product as described in section 3.1. In addition, your notification includes information about the history of use of "Coffee Tamer®" and evidence of safety produced using "Tummy Tamer®", "Food Tamer®", "Liquid Tamer®" as well as "Coffee Tamer®" but neither the full composition nor the serving levels of these products are described in your notification. Thus, it is unclear to us how these products are qualitatively and quantitatively related to the new dietary ingredient that is the subject of your notification and how the history of use and other evidence of safety for these products as described in your notification are relevant to evaluating the safe use of "pH Balance™" 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 Alka-Plex® when used under the conditions recommended or suggested in the labeling of "pH Balance™", 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 September 9, 2005. 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 Dr. Linda Pellicore at (301) 436-2375.

Sincerely yours,



Susan J. Walker, M.D.

for

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety and Applied Nutrition