



NOV 10 2005

Brent M. Burningham,
General Counsel
Albion Laboratories, Inc.
101 North Main Street
Clearfield Utah 84015

Dear Mr. Burningham:

This is to inform you that the notification, dated August 24, 2005 that you submitted on behalf of your client, Albion Laboratories, 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 29, 2005. Your notification concerns the substance called "Manganese Glucosamine Gluconate" or "Manganese Glucosamine™" that you intend to market as a new dietary ingredient for use in dietary supplement products.

According to your notification, "Manganese Glucosamine Gluconate" will be marketed in "typical dosage forms as a supplement to other sources of manganese and glucosamine in the diet." Your notification states that "Albion has concluded that Manganese Glucosamine™ is safe when administered in the range of doses calculated to satisfy either the RDA or the adult DRI upper level of manganese" which you state in your notification correspond to 100 and 220 mg of "Manganese Glucosamine™", respectively.

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) (section 402(f)(1)(B) of the Act) 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 "Manganese Glucosamine Gluconate" will reasonably be expected to be safe.

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FDA was unable to determine the identity of "Manganese Glucosamine Gluconate". Your notification provides specifications for manganese and a description of the physical attributes of "Manganese Glucosamine Gluconate" but these specifications and attributes are inadequate to describe the identity of "Manganese Glucosamine Gluconate". If your notification had provided a chemical description of your ingredient or manufacturing information FDA might have been able to determine the identity of "Manganese Glucosamine Gluconate". In addition, your notification does not provide the dosage form or describe the dietary supplement product or products that will contain your ingredient.

Your notification provides, as evidence of safety, information about the safety of manganese and glucosamine, substances that appear to be used to manufacture "Manganese Glucosamine Gluconate". However, because the identity of "Manganese Glucosamine Gluconate" is unclear, it is unclear how your ingredient is qualitatively or quantitatively similar to the substances described in the safety information you relied on in your notification or how that information is relevant to evaluating the safe use of "Manganese Glucosamine Gluconate".

In addition, your notification provides the results of an acute toxicity study in which "Manganese Glucosamine Gluconate" was administered to six rats. The finding of a rapid, 100% mortality of the test animals at the highest dose, in the absence of further relevant information, appears to not provide a basis to support a determination that chronic consumption of a dietary supplement containing "Manganese Glucosamine Gluconate" will reasonably be expected to be safe.

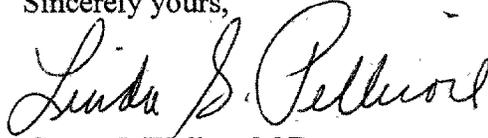
For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Manganese Glucosamine Gluconate" when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product 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 29, 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.

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

Sincerely yours,



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